# 105TH CONGRESS 2D SESSION

# H. R. 3605

To amend the Public Health Service Act, the Employee Retirement Income Security Act of 1974, and the Internal Revenue Code of 1986 to protect consumers in managed care plans and other health coverage.

# IN THE HOUSE OF REPRESENTATIVES

March 31, 1998

Mr. Dingell (for himself, Mr. Gephardt, Mr. Brown of Ohio, Mr. Ran-GEL, Mr. STARK, Mr. CLAY, Mr. PAYNE, Mr. FAZIO of California, Mr. WAXMAN, Mr. ABERCROMBIE, Mr. ALLEN, Mr. ANDREWS, Mr. BAESLER, Mr. Bentsen, Mr. Berman, Mr. Boswell, Mr. Boucher, Ms. Brown of Florida, Mr. Brown of California, Mrs. Capps, Mr. Cardin, Ms. Car-SON, Ms. CHRISTIAN-GREEN, Mrs. CLAYTON, Mr. CLEMENT, Mr. COYNE, Mr. Cummings, Ms. DeGette, Mr. Delahunt, Ms. Delauro, Ms. ESHOO, Mr. EVANS, Mr. FILNER, Mr. FORD, Mr. FRANK of Massachusetts, Mr. Frost, Ms. Furse, Mr. Gejdenson, Mr. Green, Mr. HASTINGS of Florida, Mr. HILLIARD, Mr. HINCHEY, Mr. HOYER, Mr. Jackson of Illinois, Ms. Jackson-Lee of Texas, Ms. Eddie Bernice Johnson of Texas, Ms. Kaptur, Mr. Kennedy of Massachusetts, Mrs. Kennelly of Connecticut, Mr. Klink, Mr. Lafalce, Mr. Lantos, Mr. Lewis of Georgia, Ms. Lofgren, Mrs. Maloney of New York, Mr. MANTON, Mr. MARKEY, Mr. MARTINEZ, Mr. MATSUI, Ms. McCarthy of Missouri, Mr. McGovern, Ms. McKinney, Mrs. Meek of Florida, Mr. MENENDEZ, Mr. MILLER of California, Mr. MINGE, Mr. NADLER, Ms. NORTON, Mr. OLVER, Mr. OWENS, Mr. PALLONE, Mr. PASCRELL, Ms. Pelosi, Mr. Peterson of Minnesota, Mr. Rahall, Ms. Rivers, Mr. ROMERO-BARCELÓ, Mr. SANDLIN, Mr. ROTHMAN, Mr. RUSH, Mr. SABO, Mr. Sanders, Mr. Sawyer, Mr. Serrano, Ms. Stabenow, Mr. Strick-LAND, Mr. STUPAK, Mr. THOMPSON, Mrs. THURMAN, Mr. TOWNS, Ms. VELÁZQUEZ, Mr. VENTO, Mr. WEXLER, Mr. WEYGAND, Mr. WISE, Ms. Woolsey, Mr. Wynn, and Mr. Yates) introduced the following bill; which was referred to the Committee on Commerce, and in addition to the Committees on Ways and Means, and Education and the Workforce, for a period to be subsequently determined by the Speaker, in each case for consideration of such provisions as fall within the jurisdiction of the committee concerned

# A BILL

- To amend the Public Health Service Act, the Employee Retirement Income Security Act of 1974, and the Internal Revenue Code of 1986 to protect consumers in managed care plans and other health coverage.
  - 1 Be it enacted by the Senate and House of Representa-
  - 2 tives of the United States of America in Congress assembled,
  - 3 SECTION 1. SHORT TITLE; TABLE OF CONTENTS.
  - 4 (a) SHORT TITLE.—This Act may be cited as the
  - 5 "Patients' Bill of Rights Act of 1998".
- 6 (b) Table of Contents of Contents of
- 7 this Act is as follows:
  - Sec. 1. Short title; table of contents.

#### TITLE I—HEALTH INSURANCE BILL OF RIGHTS

#### Subtitle A—Access to Care

- Sec. 101. Access to emergency care.
- Sec. 102. Offering of choice of coverage options under group health plans.
- Sec. 103. Choice of providers.
- Sec. 104. Access to specialty care.
- Sec. 105. Continuity of care.
- Sec. 106. Coverage for individuals participating in approved clinical trials.
- Sec. 107. Access to needed prescription drugs.
- Sec. 108. Adequacy of provider network.
- Sec. 109. Nondiscrimination in delivery of services.

## Subtitle B—Quality Assurance

- Sec. 111. Internal quality assurance program.
- Sec. 112. Collection of standardized data.
- Sec. 113. Process for selection of providers.
- Sec. 114. Drug utilization program.
- Sec. 115. Standards for utilization review activities.
- Sec. 116. Health Care Quality Advisory Board.

#### Subtitle C—Patient Information

- Sec. 121. Patient information.
- Sec. 122. Protection of patient confidentiality.
- Sec. 123. Health insurance ombudsmen.

#### Subtitle D—Grievance and Appeals Procedures

- Sec. 131. Establishment of grievance process.
- Sec. 132. Internal appeals of adverse determinations.
- Sec. 133. External appeals of adverse determinations.

#### Subtitle E—Protecting the Doctor-Patient Relationship

- Sec. 141. Prohibition of interference with certain medical communications.
- Sec. 142. Prohibition against transfer of indemnification or improper incentive arrangements.
- Sec. 143. Additional rules regarding participation of health care professionals.
- Sec. 144. Protection for patient advocacy.

#### Subtitle F—Promoting Good Medical Practice

- Sec. 151. Promoting good medical practice.
- Sec. 152. Standards relating to benefits for certain breast cancer treatment.
- Sec. 153. Standards relating to benefits for reconstructive breast surgery.

#### Subtitle G—Definitions

- Sec. 191. Definitions.
- Sec. 192. Preemption; State flexibility; construction.
- Sec. 193. Regulations.

# TITLE II—APPLICATION OF PATIENT PROTECTION STANDARDS TO GROUP HEALTH PLANS AND HEALTH INSURANCE COVERAGE UNDER PUBLIC HEALTH SERVICE ACT

- Sec. 201. Application to group health plans and group health insurance coverage.
- Sec. 202. Application to individual health insurance coverage.

# TITLE III—AMENDMENTS TO THE EMPLOYEE RETIREMENT INCOME SECURITY ACT OF 1974

- Sec. 301. Application of patient protection standards to group health plans and group health insurance coverage under the Employee Retirement Income Security Act of 1974.
- Sec. 302. ERISA preemption not to apply to certain actions involving health insurance policyholders.

# TITLE IV—APPLICATION TO GROUP HEALTH PLANS UNDER THE INTERNAL REVENUE CODE OF 1986

Sec. 401. Amendments to the Internal Revenue Code of 1986.

# TITLE V—EFFECTIVE DATES; COORDINATION IN IMPLEMENTATION

- Sec. 501. Effective dates.
- Sec. 502. Coordination in implementation.

# TITLE I—HEALTH INSURANCE 1 **BILL OF RIGHTS** 2 Subtitle A—Access to Care 3 SEC. 101. ACCESS TO EMERGENCY CARE. 4 5 (a) Coverage of Emergency Services.— 6 (1) IN GENERAL.—If a group health plan, or 7 health insurance coverage offered by a health insur-8 ance issuer, provides any benefits with respect to 9 emergency services (as defined in paragraph (2)(B)), 10 the plan or issuer shall cover emergency services fur-11 nished under the plan or coverage— 12 (A) without the need for any prior author-13 ization determination; 14 (B) whether or not the health care pro-15 vider furnishing such services is a participating 16 provider with respect to such services; 17 (C) in a manner so that, if such services 18 are provided to a participant, beneficiary, or en-19 rollee by a nonparticipating health care pro-20 vider— 21 (i) the participant, beneficiary, or en-22 rollee is not liable for amounts that exceed 23 the amounts of liability that would be in-24 curred if the services were provided by a 25 participating health care provider, and

1 (ii) the plan or issuer pays an amount
2 that is not less than the amount paid to a
3 participating health care provider for the
4 same services; and

(D) without regard to any other term or condition of such coverage (other than exclusion or coordination of benefits, or an affiliation or waiting period, permitted under section 2701 of the Public Health Service Act, section 701 of the Employee Retirement Income Security Act of 1974, or section 9801 of the Internal Revenue Code of 1986, and other than applicable cost-sharing).

# (2) Definitions.—In this section:

(A) EMERGENCY MEDICAL CONDITION
BASED ON PRUDENT LAYPERSON STANDARD.—
The term "emergency medical condition" means
a medical condition manifesting itself by acute
symptoms of sufficient severity (including severe pain) such that a prudent layperson, who
possesses an average knowledge of health and
medicine, could reasonably expect the absence
of immediate medical attention to result in a
condition described in clause (i), (ii), or (iii) of

1	section 1867(e)(1)(A) of the Social Security
2	Act.
3	(B) Emergency services.—The term
4	"emergency services" means—
5	(i) a medical screening examination
6	(as required under section 1867 of the So-
7	cial Security Act) that is within the capa-
8	bility of the emergency department of a
9	hospital, including ancillary services rou-
10	tinely available to the emergency depart-
11	ment to evaluate an emergency medical
12	condition (as defined in subparagraph
13	(A)), and
14	(ii) within the capabilities of the staff
15	and facilities available at the hospital, such
16	further medical examination and treatment
17	as are required under section 1867 of such
18	Act to stabilize the patient.
19	(b) Reimbursement for Maintenance Care and
20	Post-Stabilization Care.—In the case of services
21	(other than emergency services) for which benefits are
22	available under a group health plan, or under health insur-
23	ance coverage offered by a health insurance issuer, the
24	plan or issuer shall provide for reimbursement with re-
25	spect to such services provided to a participant, bene-

- 1 ficiary, or enrollee other than through a participating
- 2 health care provider in a manner consistent with sub-
- 3 section (a)(1)(C) if the services are maintenance care or
- 4 post-stabilization care covered under the guidelines estab-
- 5 lished under section 1852(d)(2) of the Social Security Act
- 6 (relating to promoting efficient and timely coordination of
- 7 appropriate maintenance and post-stabilization care of an
- 8 enrollee after an enrollee has been determined to be sta-
- 9 ble), or, in the absence of guidelines under such section,
- 10 such guidelines as the Secretary shall establish to carry
- 11 out this subsection.
- 12 SEC. 102. OFFERING OF CHOICE OF COVERAGE OPTIONS
- 13 UNDER GROUP HEALTH PLANS.
- 14 (a) Requirement.—
- 15 (1) Offering of Point-of-Service Cov-
- 16 ERAGE OPTION.—Except as provided in paragraph
- 17 (2), if a group health plan (or health insurance cov-
- erage offered by a health insurance issuer in connec-
- tion with a group health plan) provides benefits only
- through participating health care providers, the plan
- or issuer shall offer the participant the option to
- purchase point-of-service coverage (as defined in
- subsection (b)) for all such benefits for which cov-
- erage is otherwise so limited. Such option shall be
- 25 made available to the participant at the time of en-

1	rollment under the plan or coverage and at such
2	other times as the plan or issuer offers the partici-
3	pant a choice of coverage options.
4	(2) Exception.—Paragraph (1) shall not
5	apply with respect to a participant in a group health
6	plan if the plan offers the participant—
7	(A) a choice of health insurance coverage
8	through more than one health insurance issuer;
9	or
10	(B) two or more coverage options that dif-
11	fer significantly with respect to the use of par-
12	ticipating health care providers or the networks
13	of such providers that are used.
14	(b) Point-of-Service Coverage Defined.—In
15	this section, the term "point-of-service coverage" means,
16	with respect to benefits covered under a group health plan
17	or health insurance issuer, coverage of such benefits when
18	provided by a nonparticipating health care provider. Such
19	coverage need not include coverage of providers that the
20	plan or issuer excludes because of fraud, quality, or similar
21	reasons.
22	(e) Construction.—Nothing in this section shall be
23	construed—
24	(1) as requiring coverage for benefits for a par-

ticular type of health care provider;

- 1 (2) as requiring an employer to pay any costs 2 as a result of this section or to make equal contribu-3 tions with respect to different health coverage op-
- 5 (3) as preventing a group health plan or health 6 insurance issuer from imposing higher premiums or 7 cost-sharing on a participant for the exercise of a 8 point-of-service coverage option.
- 9 (d) No Requirement for Guaranteed Avail-10 ability.—If a health insurance issuer offers health insur-11 ance coverage that includes point-of-service coverage with
- 12 respect to an employer solely in order to meet the require-
- 13 ment of subsection (a), nothing in section 2711(a)(1)(A)
- 14 of the Public Health Service Act shall be construed as re-
- 15 quiring the offering of such coverage with respect to an-
- 16 other employer.

tions; or

### 17 SEC. 103. CHOICE OF PROVIDERS.

- 18 (a) Primary Care.—A group health plan, and a
- 19 health insurance issuer that offers health insurance cov-
- 20 erage, shall permit each participant, beneficiary, and en-
- 21 rollee to receive primary care from any participating pri-
- 22 mary care provider who is available to accept such individ-
- 23 ual.
- 24 (b) Specialists.—

- (1) In General.—Subject to paragraph (2), a group health plan and a health insurance issuer that offers health insurance coverage shall permit each participant, beneficiary, or enrollee to receive medi-cally necessary or appropriate specialty care, pursu-ant to appropriate referral procedures, from any qualified participating health care provider who is available to accept such individual for such care.
  - (2) LIMITATION.—Paragraph (1) shall not apply to specialty care if the plan or issuer clearly informs participants, beneficiaries, and enrollees of the limitations on choice of participating providers with respect to such care.

## 14 SEC. 104. ACCESS TO SPECIALTY CARE.

- (a) Obstetrical and Gynecological Care.—
- (1) In General.—If a group health plan, or a health insurance issuer in connection with the provision of health insurance coverage, requires or provides for a participant, beneficiary, or enrollee to designate a participating primary care provider—
  - (A) the plan or issuer shall permit such an individual who is a female to designate a participating physician who specializes in obstetrics and gynecology as the individual's primary care provider; and

1	(B) if such an individual has not des-
2	ignated such a provider as a primary care pro-
3	vider, the plan or issuer—
4	(i) may not require authorization or a
5	referral by the individual's primary care
6	provider or otherwise for coverage of rou-
7	tine gynecological care (such as preventive
8	women's health examinations) and preg-
9	nancy-related services provided by a par-
10	ticipating health care professional who spe-
11	cializes in obstetrics and gynecology to the
12	extent such care is otherwise covered, and
13	(ii) may treat the ordering of other
14	gynecological care by such a participating
15	physician as the authorization of the pri-
16	mary care provider with respect to such
17	care under the plan or coverage.
18	(2) Construction.—Nothing in paragraph
19	(1)(B)(ii) shall waive any requirements of coverage
20	relating to medical necessity or appropriateness with
21	respect to coverage of gynecological care so ordered.
22	(b) Specialty Care.—
23	(1) Specialty care for covered serv-
24	ICES.—
25	(A) In general.—If—

1	(i) an individual is a participant or
2	beneficiary under a group health plan or
3	an enrollee who is covered under health in-
4	surance coverage offered by a health insur-
5	ance issuer,
6	(ii) the individual has a condition or
7	disease of sufficient seriousness and com-
8	plexity to require treatment by a specialist,
9	and
10	(iii) benefits for such treatment are
11	provided under the plan or coverage,
12	the plan or issuer shall make or provide for a
13	referral to a specialist who is available and ac-
14	cessible to provide the treatment for such condi-
15	tion or disease.
16	(B) Specialist defined.—For purposes
17	of this subsection, the term "specialist" means,
18	with respect to a condition, a health care practi-
19	tioner, facility, or center (such as a center of
20	excellence) that has adequate expertise through
21	appropriate training and experience (including,
22	in the case of a child, appropriate pediatric ex-
23	pertise) to provide high quality care in treating

the condition.

1	(C) CARE UNDER REFERRAL.—A group
2	health plan or health insurance issuer may re-
3	quire that the care provided to an individual
4	pursuant to such referral under subparagraph
5	(A) be—
6	(i) pursuant to a treatment plan, only
7	if the treatment plan is developed by the
8	specialist and approved by the plan or
9	issuer, in consultation with the designated
10	primary care provider or specialist and the
11	individual (or the individual's designee),
12	and
13	(ii) in accordance with applicable
14	quality assurance and utilization review
15	standards of the plan or issuer.
16	Nothing in this subsection shall be construed as
17	preventing such a treatment plan for an individ-
18	ual from requiring a specialist to provide the
19	primary care provider with regular updates on
20	the specialty care provided, as well as all nec-
21	essary medical information.
22	(D) Referrals to participating pro-
23	VIDERS.—A group health plan or health insur-
24	ance issuer is not required under subparagraph
25	(A) to provide for a referral to a specialist that

is not a participating provider, unless the plan or issuer does not have an appropriate specialist that is available and accessible to treat the individual's condition and that is a participating provider with respect to such treatment.

- (E) TREATMENT OF NONPARTICIPATING PROVIDERS.—If a plan or issuer refers an individual to a nonparticipating specialist pursuant to subparagraph (A), services provided pursuant to the approved treatment plan (if any) shall be provided at no additional cost to the individual beyond what the individual would otherwise pay for services received by such a specialist that is a participating provider.
- (2) Specialists as primary care providers.—

(A) In General.—A group health plan, or a health insurance issuer, in connection with the provision of health insurance coverage, shall have a procedure by which an individual who is a participant, beneficiary, or enrollee and who has an ongoing special condition (as defined in subparagraph (C)) may receive a referral to a specialist for such condition who shall be responsible for and capable of providing and co-

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sions of subparagraphs (C) through (E) of

paragraph (1) apply with respect to referrals

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under subparagraph (A) of this paragraph in the same manner as they apply to referrals under paragraph (1)(A).

# (3) Standing referrals.—

(A) In General.—A group health plan, and a health insurance issuer in connection with the provision of health insurance coverage, shall have a procedure by which an individual who is a participant, beneficiary, or enrollee and who has a condition that requires ongoing care from a specialist may receive a standing referral to such specialist for treatment of such condition. If the plan or issuer, or if the primary care provider in consultation with the medical director of the plan or issuer and the specialist (if any), determines that such a standing referral is appropriate, the plan or issuer shall make such a referral to such a specialist.

(B) TERMS OF REFERRAL.—The provisions of subparagraphs (C) through (E) of paragraph (1) apply with respect to referrals under subparagraph (A) of this paragraph in the same manner as they apply to referrals under paragraph (1)(A).

## SEC. 105. CONTINUITY OF CARE.

(a)	$I_{N}$	GENERAL.—
\ a i	T11	OENERAL.—

- (1) TERMINATION OF PROVIDER.—If a contract between a group health plan, or a health insurance issuer in connection with the provision of health insurance coverage, and a health care provider is terminated (as defined in paragraph (3)), or benefits or coverage provided by a health care provider are terminated because of a change in the terms of provider participation in a group health plan, and an individual who is a participant, beneficiary, or enrollee in the plan or coverage is undergoing a course of treatment from the provider at the time of such termination, the plan or issuer shall—
  - (A) notify the individual on a timely basis of such termination, and
  - (B) subject to subsection (c), permit the individual to continue or be covered with respect to the course of treatment with the provider during a transitional period (provided under subsection (b)).
- (2) Treatment of termination of contract with health insurance issuer.—If a contract for the provision of health insurance coverage between a group health plan and a health insurance issuer is terminated and, as a result of such

termination, coverage of services of a health care provider is terminated with respect to an individual, the provisions of paragraph (1) (and the succeeding provisions of this section) shall apply under the plan in the same manner as if there had been a contract between the plan and the provider that had been terminated, but only with respect to benefits that are covered under the plan after the contract termination.

(3) TERMINATION.—In this section, the term "terminated" includes, with respect to a contract, the expiration or nonrenewal of the contract, but does not include a termination of the contract by the plan or issuer for failure to meet applicable quality standards or for fraud.

## (b) Transitional Period.—

- (1) IN GENERAL.—Except as provided in paragraphs (2) through (4), the transitional period under this subsection shall extend for at least 90 days from the date of the notice described in subsection (a)(1)(A) of the provider's termination.
- (2) Institutional care.—The transitional period under this subsection for institutional or inpatient care from a provider shall extend until the discharge or termination of the period of institutional-

ization and also shall include institutional care provided within a reasonable time of the date of termination of the provider status if the care was scheduled before the date of the announcement of the termination of the provider status under subsection (a)(1)(A) or if the individual on such date was on an established waiting list or otherwise scheduled to have such care.

## (3) Pregnancy.—If—

(A) a participant, beneficiary, or enrollee has entered the second trimester of pregnancy at the time of a provider's termination of participation, and

(B) the provider was treating the preg-

nancy before date of the termination,
the transitional period under this subsection with respect to provider's treatment of the pregnancy shall
extend through the provision of post-partum care directly related to the delivery.

# (4) TERMINAL ILLNESS.—If—

(A) a participant, beneficiary, or enrollee was determined to be terminally ill (as determined under section 1861(dd)(3)(A) of the Social Security Act) at the time of a provider's termination of participation, and

- 1 (B) the provider was treating the terminal 2 illness before the date of termination,
- the transitional period under this subsection shall extend for the remainder of the individual's life for care directly related to the treatment of the terminal
- 7 (c) PERMISSIBLE TERMS AND CONDITIONS.—A
  8 group health plan or health insurance issuer may condi9 tion coverage of continued treatment by a provider under
  10 subsection (a)(1)(B) upon the provider agreeing to the fol11 lowing terms and conditions:
- 12 (1) The provider agrees to accept reimburse-13 ment from the plan or issuer and individual involved 14 (with respect to cost-sharing) at the rates applicable 15 prior to the start of the transitional period as pay-16 ment in full (or, in the case described in subsection 17 (a)(2), at the rates applicable under the replacement 18 plan or issuer after the date of the termination of 19 the contract with the health insurance issuer) and 20 not to impose cost-sharing with respect to the indi-21 vidual in an amount that would exceed the cost-shar-22 ing that could have been imposed if the contract re-23 ferred to in subsection (a)(1) had not been termi-24 nated.

illness.

- 1 (2) The provider agrees to adhere to the quality 2 assurance standards of the plan or issuer responsible 3 for payment under paragraph (1) and to provide to 4 such plan or issuer necessary medical information 5 related to the care provided.
  - (3) The provider agrees otherwise to adhere to such plan's or issuer's policies and procedures, including procedures regarding referrals and obtaining prior authorization and providing services pursuant to a treatment plan (if any) approved by the plan or issuer.
- 12 (d) Construction.—Nothing in this section shall be 13 construed to require the coverage of benefits which would 14 not have been covered if the provider involved remained 15 a participating provider.
- 16 SEC. 106. COVERAGE FOR INDIVIDUALS PARTICIPATING IN
  17 APPROVED CLINICAL TRIALS.
- 18 (a) Coverage.—

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19 (1) IN GENERAL.—If a group health plan, or 20 health insurance issuer that is providing health in-21 surance coverage, provides coverage to a qualified in-22 dividual (as defined in subsection (b)), the plan or 23 issuer—

- 1 (A) may not deny the individual participa-2 tion in the clinical trial referred to in subsection 3 (b)(2);
  - (B) subject to subsection (c), may not deny (or limit or impose additional conditions on) the coverage of routine patient costs for items and services furnished in connection with participation in the trial; and
  - (C) may not discriminate against the individual on the basis of the enrollee's participation in such trial.
  - (2) Exclusion of Certain Costs.—For purposes of paragraph (1)(B), routine patient costs do not include the cost of the tests or measurements conducted primarily for the purpose of the clinical trial involved.
  - (3) USE OF IN-NETWORK PROVIDERS.—If one or more participating providers is participating in a clinical trial, nothing in paragraph (1) shall be construed as preventing a plan or issuer from requiring that a qualified individual participate in the trial through such a participating provider if the provider will accept the individual as a participant in the trial.

1	(b) Qualified Individual Defined.—For pur-
2	poses of subsection (a), the term "qualified individual"
3	means an individual who is a participant or beneficiary
4	in a group health plan, or who is an enrollee under health
5	insurance coverage, and who meets the following condi-
6	tions:
7	(1)(A) The individual has a life-threatening or
8	serious illness for which no standard treatment is ef-
9	fective.
10	(B) The individual is eligible to participate in
11	an approved clinical trial according to the trial pro-
12	tocol with respect to treatment of such illness.
13	(C) The individual's participation in the trial
14	offers meaningful potential for significant clinical
15	benefit for the individual.
16	(2) Either—
17	(A) the referring physician is a participat-
18	ing health care professional and has concluded
19	that the individual's participation in such trial
20	would be appropriate based upon the individual
21	meeting the conditions described in paragraph
22	(1); or
23	(B) the participant, beneficiary, or enrollee
24	provides medical and scientific information es-
25	tablishing that the individual's participation in

1 such trial would be appropriate based upon the 2 individual meeting the conditions described in 3 paragraph (1). 4 (c) Payment.— (1) In General.—Under this section a group 5 6 health plan or health insurance issuer shall provide 7 for payment for routine patient costs described in 8 subsection (a)(2) but is not required to pay for costs 9 of items and services that are reasonably expected 10 (as determined by the Secretary) to be paid for by 11 the sponsors of an approved clinical trial. 12 (2) Payment rate.—In the case of covered 13 items and services provided by— 14 (A) a participating provider, the payment 15 rate shall be at the agreed upon rate, or 16 (B) a nonparticipating provider, the pay-17 ment rate shall be at the rate the plan or issuer 18 would normally pay for comparable services 19 under subparagraph (A). 20 (d) APPROVED CLINICAL TRIAL DEFINED.— 21 (1) IN GENERAL.—In this section, the term "approved clinical trial" means a clinical research 22 23 study or clinical investigation approved and funded 24 (which may include funding through in-kind con-

tributions) by one or more of the following:

1	(A) The National Institutes of Health.
2	(B) A cooperative group or center of the
3	National Institutes of Health.
4	(C) Either of the following if the condi-
5	tions described in paragraph (2) are met:
6	(i) The Department of Veterans Af-
7	fairs.
8	(ii) The Department of Defense.
9	(2) Conditions for Departments.—The
10	conditions described in this paragraph, for a study
11	or investigation conducted by a Department, are
12	that the study or investigation has been reviewed
13	and approved through a system of peer review that
14	the Secretary determines—
15	(A) to be comparable to the system of peer
16	review of studies and investigations used by the
17	National Institutes of Health, and
18	(B) assures unbiased review of the highest
19	scientific standards by qualified individuals who
20	have no interest in the outcome of the review.
21	(e) Construction.—Nothing in this section shall be
22	construed to limit a plan's or issuer's coverage with re-
23	spect to clinical trials.

# $1\;$ sec. 107. Access to needed prescription drugs.

2	(a) In General.—If a group health plan, or health
3	insurance issuer that offers health insurance coverage,
4	provides benefits with respect to prescription drugs but
5	the coverage limits such benefits to drugs included in a
6	formulary, the plan or issuer shall—
7	(1) ensure participation of participating physi-
8	cians and pharmacists in the development of the for-
9	mulary;
10	(2) disclose to providers and, disclose upon re-
11	quest under section 121(c)(6) to participants, bene-
12	ficiaries, and enrollees, the nature of the formulary
13	restrictions; and
14	(3) consistent with the standards for a utiliza-
15	tion review program under section 115, provide for
16	exceptions from the formulary limitation when a
17	non-formulary alternative is medically indicated.
18	(b) Coverage of Approved Drugs and Medical
19	DEVICES.—
20	(1) In general.—A group health plan (or
21	health insurance coverage offered in connection with
22	such a plan) that provides any coverage of prescrip-
23	tion drugs or medical devices shall not deny coverage
24	of such a drug or device on the basis that the use
25	is investigational, if the use—
26	(A) in the case of a prescription drug—

1	(i) is included in the labeling author-
2	ized by the application in effect for the
3	drug pursuant to subsection (b) or (j) or
4	section 505 of the Federal Food, Drug
5	and Cosmetic Act, without regard to any
6	postmarketing requirements that may
7	apply under such Act; or
8	(ii) is included in the labeling author-
9	ized by the application in effect for the
10	drug under section 351 of the Public
11	Health Service Act, without regard to any
12	postmarketing requirements that may
13	apply pursuant to such section; or
14	(B) in the case of a medical device, is in-
15	cluded in the labeling authorized by a regula-
16	tion under subsection (d) or (3) of section 513
17	of the Federal Food, Drug, and Cosmetic Act
18	an order under subsection (f) of such section, or
19	an application approved under section 515 or
20	such Act, without regard to any postmarketing
21	requirements that may apply under such Act.
22	(2) Construction.—Nothing in this sub-
23	section shall be construed as requiring a group

health plan (or health insurance coverage offered in

- 1 connection with such a plan) to provide any coverage
- 2 of prescription drugs or medical devices.

# 3 SEC. 108. ADEQUACY OF PROVIDER NETWORK.

- 4 (a) In General.—Each group health plan, and each
- 5 health insurance issuer offering health insurance coverage,
- 6 that provides benefits, in whole or in part, through partici-
- 7 pating health care providers shall have (in relation to the
- 8 coverage) a sufficient number, distribution, and variety of
- 9 qualified participating health care providers to ensure that
- 10 all covered health care services, including specialty serv-
- 11 ices, will be available and accessible in a timely manner
- 12 to all participants, beneficiaries, and enrollees under the
- 13 plan or coverage.
- 14 (b) Treatment of Certain Providers.—The
- 15 qualified health care providers under subsection (a) may
- 16 include Federally qualified health centers, rural health
- 17 clinics, migrant health centers, and other essential com-
- 18 munity providers located in the service area of the plan
- 19 or issuer and shall include such providers if necessary to
- 20 meet the standards established to carry out such sub-
- 21 section.

# 22 SEC. 109. NONDISCRIMINATION IN DELIVERY OF SERVICES.

- 23 (a) Application to Delivery of Services.—Sub-
- 24 ject to subsection (b), a group health plan, and health in-
- 25 surance issuer in relation to health insurance coverage,

- 1 may not discriminate against a participant, beneficiary, or
- 2 enrollee in the delivery of health care services consistent
- 3 with the benefits covered under the plan or coverage or
- 4 as required by law based on race, color, ethnicity, national
- 5 origin, religion, sex, age, mental or physical disability, sex-
- 6 ual orientation, genetic information, or source of payment.
- 7 (b) Construction.—Nothing in subsection (a) shall
- 8 be construed as relating to the eligibility to be covered,
- 9 or the offering (or guaranteeing the offer) of coverage,
- 10 under a plan or health insurance coverage, the application
- 11 of any pre-existing condition exclusion consistent with ap-
- 12 plicable law, or premiums charged under such plan or cov-
- 13 erage.

# 14 Subtitle B—Quality Assurance

- 15 SEC. 111. INTERNAL QUALITY ASSURANCE PROGRAM.
- 16 (a) REQUIREMENT.—A group health plan, and a
- 17 health insurance issuer that offers health insurance cov-
- 18 erage, shall establish and maintain an ongoing, internal
- 19 quality assurance and continuous quality improvement
- 20 program that meets the requirements of subsection (b).
- 21 (b) Program Requirements.—The requirements of
- 22 this subsection for a quality improvement program of a
- 23 plan or issuer are as follows:

1	(1) Administration.—The plan or issuer has
2	a separate identifiable unit with responsibility for
3	administration of the program.
4	(2) Written Plan.—The plan or issuer has a
5	written plan for the program that is updated annu-
6	ally and that specifies at least the following:
7	(A) The activities to be conducted.
8	(B) The organizational structure.
9	(C) The duties of the medical director.
10	(D) Criteria and procedures for the assess-
11	ment of quality.
12	(3) Systematic review.—The program pro-
13	vides for systematic review of the type of health
14	services provided, consistency of services provided
15	with good medical practice, and patient outcomes.
16	(4) QUALITY CRITERIA.—The program—
17	(A) uses criteria that are based on per-
18	formance and patient outcomes where feasible
19	and appropriate;
20	(B) includes criteria that are directed spe-
21	cifically at meeting the needs of at-risk popu-
22	lations and covered individuals with chronic
23	conditions or severe illnesses, including gender-
24	specific criteria and pediatric-specific criteria
25	where available and appropriate;

1	(C) includes methods for informing covered
2	individuals of the benefit of preventive care and
3	what specific benefits with respect to preventive
4	care are covered under the plan or coverage
5	and
6	(D) makes available to the public a de-
7	scription of the criteria used under subpara-
8	graph (A).
9	(5) System for reporting.—The program
10	has procedures for reporting of possible quality con-
11	cerns by providers and enrollees and for remedial ac-
12	tions to correct quality problems, including written
13	procedures for responding to concerns and taking
14	appropriate corrective action.
15	(6) Data analysis.—The program provides
16	using data that include the data collected under sec-
17	tion 112, for an analysis of the plan's or issuer's
18	performance on quality measures.
19	(7) Drug utilization review.—The program
20	provides for a drug utilization review program in ac-
21	cordance with section 114.
22	(c) Deeming.—For purposes of subsection (a), the
23	requirements of—
24	(1) subsection (b) (other than paragraph (5))

are deemed to be met with respect to a health insur-

- 1 ance issuer that is a qualified health maintenance
- 2 organization (as defined in section 1310(c) of the
- 3 Public Health Service Act); or
- 4 (2) subsection (b) are deemed to be met with
- 5 respect to a health insurance issuer that is accred-
- 6 ited by a national accreditation organization that the
- 7 Secretary certifies as applying, as a condition of cer-
- 8 tification, standards at least a stringent as those re-
- 9 quired for a quality improvement program under
- subsection (b).
- 11 (d) Variation Permitted.—The Secretary may
- 12 provide for variations in the application of the require-
- 13 ments of this section to group health plans and health in-
- 14 surance issuers based upon differences in the delivery sys-
- 15 tem among such plans and issuers as the Secretary deems
- 16 appropriate.

### 17 SEC. 112. COLLECTION OF STANDARDIZED DATA.

- 18 (a) IN GENERAL.—A group health plan and a health
- 19 insurance issuer that offers health insurance coverage
- 20 shall collect uniform quality data that include a minimum
- 21 uniform data set described in subsection (b).
- 22 (b) Minimum Uniform Data Set.—The Secretary
- 23 shall specify (and may from time to time update) the data
- 24 required to be included in the minimum uniform data set

- 1 under subsection (a) and the standard format for such
- 2 data. Such data shall include at least—
- 3 (1) aggregate utilization data;
- 4 (2) data on the demographic characteristics of participants, beneficiaries, and enrollees;
- 6 (3) data on disease-specific and age-specific
  7 mortality rates and (to the extent feasible) morbidity
  8 rates of such individuals;
- 9 (4) data on satisfaction of such individuals, in-10 cluding data on voluntary disenrollment and griev-11 ances; and
- 12 (5) data on quality indicators and health out-13 comes, including, to the extent feasible and appro-14 priate, data on pediatric cases and on a gender-spe-15 cific basis.
- 16 (c) AVAILABILITY.—A summary of the data collected 17 under subsection (a) shall be disclosed under section 18 121(b)(9). The Secretary shall be provided access to all 19 the data so collected.
- 20 (d) Variation Permitted.—The Secretary may 21 provide for variations in the application of the require-22 ments of this section to group health plans and health in-23 surance issuers based upon differences in the delivery sys-24 tem among such plans and issuers as the Secretary deems

25 appropriate.

# 1 SEC. 113. PROCESS FOR SELECTION OF PROVIDERS.

2	(a) In General.—A group health plan and a health
3	insurance issuer that offers health insurance coverage
4	shall, if it provides benefits through participating health
5	care professionals, have a written process for the selection
6	of participating health care professionals, including mini-
7	mum professional requirements.
8	(b) Verification of Background.—Such process
9	shall include verification of a health care provider's license
10	and a history of suspension or revocation.
11	(e) Restriction.—Such process shall not use a
12	high-risk patient base or location of a provider in an area
13	with residents with poorer health status as a basis for ex-
14	cluding providers from participation.
15	(d) Nondiscrimination Based on Licensure.—
16	(1) In general.—Such process shall not dis-
17	criminate with respect to participation or indem-
18	nification as to any provider who is acting within the
19	scope of the provider's license or certification under
20	applicable State law, solely on the basis of such li-
21	cense or certification.
22	(2) Construction.—Paragraph (1) shall not
23	be construed—
24	(A) as requiring the coverage under a plan
25	or coverage of particular benefits or services or
26	to prohibit a plan or issuer from including pro-

viders only to the extent necessary to meet the needs of the plan's or issuer's participants, beneficiaries, or enrollees or from establishing any measure designed to maintain quality and control costs consistent with the responsibilities of the plan or issuer; or

(B) to override any State licensure or scope-of-practice law.

# (e) General Nondiscrimination.—

- (1) In General.—Subject to paragraph (2), such process shall not discriminate with respect to selection of a health care professional to be a participating health care provider, or with respect to the terms and conditions of such participation, based on the professional's race, color, religion, sex, national origin, age, sexual orientation, or disability (consistent with the Americans with Disabilities Act of 1990).
- (2) Rules.—The appropriate Secretary may establish such definitions, rules, and exceptions as may be appropriate to carry out paragraph (1), taking into account comparable definitions, rules, and exceptions in effect under employment-based non-discrimination laws and regulations that relate to

1	each of the particular bases for discrimination de-
2	scribed in such paragraph.
3	SEC. 114. DRUG UTILIZATION PROGRAM.
4	A group health plan, and a health insurance issuer
5	that provides health insurance coverage, that includes ben-
6	efits for prescription drugs shall establish and maintain,
7	as part of its internal quality assurance and continuous
8	quality improvement program under section 111, a drug
9	utilization program which—
10	(1) encourages appropriate use of prescription
11	drugs by participants, beneficiaries, and enrollees
12	and providers, and
13	(2) takes appropriate action to reduce the inci-
14	dence of improper drug use and adverse drug reac-
15	tions and interactions.
16	SEC. 115. STANDARDS FOR UTILIZATION REVIEW ACTIVI-
17	TIES.
18	(a) Compliance with Requirements.—
19	(1) In general.—A group health plan, and a
20	health insurance issuer that provides health insur-
21	ance coverage, shall conduct utilization review activi-
22	ties in connection with the provision of benefits
23	under such plan or coverage only in accordance with
24	a utilization review program that meets the require-

ments of this section.

- (2) Use of outside agents.—Nothing in this section shall be construed as preventing a group health plan or health insurance issuer from arranging through a contract or otherwise for persons or entities to conduct utilization review activities on behalf of the plan or issuer, so long as such activities are conducted in accordance with a utilization review program that meets the requirements of this section.
  - (3) Utilization review defined.—For purposes of this section, the terms "utilization review" and "utilization review activities" mean procedures used to monitor or evaluate the clinical necessity, appropriateness, efficacy, or efficiency of health care services, procedures or settings, and includes prospective review, concurrent review, second opinions, case management, discharge planning, or retrospective review.

## (b) Written Policies and Criteria.—

(1) Written Policies.—A utilization review program shall be conducted consistent with written policies and procedures that govern all aspects of the program.

#### (2) Use of written criteria.—

(A) IN GENERAL.—Such a program shall utilize written clinical review criteria developed

pursuant to the program with the input of appropriate physicians. Such criteria shall include written clinical review criteria described in section 111(b)(4)(B).

(B) Continuing use of standards in Retrospective Review.—If a health care service has been specifically pre-authorized or approved for an enrollee under such a program, the program shall not, pursuant to retrospective review, revise or modify the specific standards, criteria, or procedures used for the utilization review for procedures, treatment, and services delivered to the enrollee during the same course of treatment.

### (c) Conduct of Program Activities.—

- (1) Administration by Health care professionals.—A utilization review program shall be administered by qualified health care professionals who shall oversee review decisions. In this subsection, the term "health care professional" means a physician or other health care practitioner licensed, accredited, or certified to perform specified health services consistent with State law.
- (2) Use of qualified, independent personnel.—

1	(A) IN GENERAL A utilization region
	(A) In General.—A utilization review
2	program shall provide for the conduct of utiliza-
3	tion review activities only through personnel
4	who are qualified and, to the extent required
5	who have received appropriate training in the
6	conduct of such activities under the program.
7	(B) Peer review of sample of ad-
8	verse clinical determinations.—Such a
9	program shall provide that clinical peers (as de-
10	fined in section $191(c)(2)$ ) shall evaluate the
11	clinical appropriateness of at least a sample of
12	adverse clinical determinations.
13	(C) Prohibition of contingent com-
14	PENSATION ARRANGEMENTS.—Such a program
15	shall not, with respect to utilization review ac-
16	tivities, permit or provide compensation or any-
17	thing of value to its employees, agents, or con-
18	tractors in a manner that—
19	(i) provides incentives, direct or indi-
20	rect, for such persons to make inappropri-
21	ate review decisions, or
22	(ii) is based, directly or indirectly, or
23	the quantity or type of adverse determina-
24	tions rendered.

- 1 (D) Prohibition of conflicts.—Such a
  2 program shall not permit a health care profes3 sional who provides health care services to an
  4 individual to perform utilization review activi-
- 5 ties in connection with the health care services
- 6 being provided to the individual.

- (3) Accessibility of Review.—Such a program shall provide that appropriate personnel performing utilization review activities under the program are reasonably accessible by toll-free telephone during normal business hours to discuss patient care and allow response to telephone requests, and that appropriate provision is made to receive and respond promptly to calls received during other hours.
- (4) LIMITS ON FREQUENCY.—Such a program shall not provide for the performance of utilization review activities with respect to a class of services furnished to an individual more frequently than is reasonably required to assess whether the services under review are medically necessary or appropriate.
- (5) Limitation on information requests.— Under such a program, information shall be required to be provided by health care providers only to the extent it is necessary to perform the utilization review activity involved.

(6) Review of preliminary utilization review decision.—Under such program a participant, beneficiary, or enrollee or any provider acting on behalf of such an individual with the individual's consent, who is dissatisfied with a preliminary utilization review decision has the opportunity to discuss the decision with, and have such decision reviewed by, the medical director of the plan or issuer involved (or the director's designee) who has the authority to reverse the decision.

#### (d) Deadline for Determinations.—

(1) Prior authorization services.—Except as provided in paragraph (2), in the case of a utilization review activity involving the prior authorization of health care items and services for an individual, the utilization review program shall make a determination concerning such authorization, and provide notice of the determination to the individual or the individual's designee and the individual's health care provider by telephone and in printed form, as soon as possible in accordance with the medical exigencies of the cases, and in no event later than 3 business days after the date of receipt of information that is reasonably necessary to make such determination.

(2) Continued care.—In the case of a utiliza-

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2 tion review activity involving authorization for continued or extended health care services for an indi-3 vidual, or additional services for an individual under-5 going a course of continued treatment prescribed by 6 a health care provider, the utilization review pro-7 gram shall make a determination concerning such 8 authorization, and provide notice of the determina-9 tion to the individual or the individual's designee 10 and the individual's health care provider by telephone and in printed form, as soon as possible in ac-12 cordance with the medical exigencies of the cases, 13 and in no event later than 1 business day after the 14 date of receipt of information that is reasonably nec-15 essary to make such determination. Such notice shall 16 include, with respect to continued or extended health 17 care services, the number of extended services ap-18 proved, the new total of approved services, the date 19 of onset of services, and the next review date, if any. 20 (3) Previously provided services.—In the

case of a utilization review activity involving retrospective review of health care services previously provided for an individual, the utilization review program shall make a determination concerning such services, and provide notice of the determination to

the individual or the individual's designee and the individual's health care provider by telephone and in printed form, within 30 days of the date of receipt of information that is reasonably necessary to make such determination.

(4) REFERENCE TO SPECIAL RULES FOR EMER-GENCY SERVICES, MAINTENANCE CARE, AND POST-STABILIZATION CARE.—For waiver of prior authorization requirements in certain cases involving emergency services and maintenance care and post-stabilization care, see subsections (a)(1) and (b) of section 101, respectively.

## (e) Notice of Adverse Determinations.—

- (1) In General.—Notice of an adverse determination under a utilization review program shall be provided in printed form and shall include—
  - (A) the reasons for the determination (including the clinical rationale);
    - (B) instructions on how to initiate an appeal under section 132; and
    - (C) notice of the availability, upon request of the individual (or the individual's designee) of the clinical review criteria relied upon to make such determination.

1	(2) Specification of any additional infor-
2	MATION.—Such a notice shall also specify what (if
3	any) additional necessary information must be pro-
4	vided to, or obtained by, the person making the de-
5	termination in order to make a decision on such an
6	appeal.
7	SEC. 116. HEALTH CARE QUALITY ADVISORY BOARD.
8	(a) Establishment.—The President shall establish
9	an advisory board to provide information to Congress and
10	the administration on issues relating to quality monitoring
11	and improvement in the health care provided under group
12	health plans and health insurance coverage.
13	(b) Number and Appointment.—The advisory
14	board shall be composed of the Secretary of Health and
15	Human Services (or the Secretary's designee), the Sec-
16	retary of Labor (or the Secretary's designee), and 20 addi-
17	tional members appointed by the President, in consulta-
18	tion with the Majority and Minority Leaders of the Senate
19	and House of Representatives. The members so appointed
20	shall include individuals with expertise in—
21	(1) consumer needs;
22	(2) education and training of health profes-
23	sionals;
24	(3) health care services;
25	(4) health plan management;

1	(5) health care accreditation, quality assurance,
2	improvement, measurement, and oversight;
3	(6) medical practice, including practicing physi-
4	cians;
5	(7) prevention and public health; and
6	(8) public and private group purchasing for
7	small and large employers or groups.
8	(c) Duties.—The advisory board shall—
9	(1) identify, update, and disseminate measures
10	of health care quality for group health plans and
11	health insurance issuers, including network and non-
12	network plans;
13	(2) advise the Secretary on the development
14	and maintenance of the minimum data set in section
15	112(b); and
16	(3) advise the Secretary on standardized for-
17	mats for information on group health plans and
18	health insurance coverage.
19	The measures identified under paragraph (1) may be used
20	on a voluntary basis by such plans and issuers. In carrying
21	out paragraph (1), the advisory board shall consult and
22	cooperate with national health care standard setting bod-
23	ies which define quality indicators, the Agency for Health
24	Care Policy and Research, the Institute of Medicine, and

- 1 other public and private entities that have expertise in
- 2 health care quality.
- 3 (d) Report.—The advisory board shall provide an
- 4 annual report to Congress and the President on the qual-
- 5 ity of the health care in the United States and national
- 6 and regional trends in health care quality. Such report
- 7 shall include a description of determinants of health care
- 8 quality and measurements of practice and quality varia-
- 9 bility within the United States.
- 10 (e) Secretarial Consultation.—In serving on
- 11 the advisory board, the Secretaries of Health and Human
- 12 Services and Labor (or their designees) shall consult with
- 13 the Secretaries responsible for other Federal health insur-
- 14 ance and health care programs.
- 15 (f) VACANCIES.—Any vacancy on the board shall be
- 16 filled in such manner as the original appointment. Mem-
- 17 bers of the board shall serve without compensation but
- 18 shall be reimbursed for travel, subsistence, and other nec-
- 19 essary expenses incurred by them in the performance of
- 20 their duties. Administrative support, scientific support,
- 21 and technical assistance for the advisory board shall be
- 22 provided by the Secretary of Health and Human Services.
- 23 (g) Continuation.—Section 14(a)(2)(B) of the
- 24 Federal Advisory Committee Act (5 U.S.C. App.; relating

1	to the termination of advisory committees) shall not apply
2	to the advisory board.
3	Subtitle C—Patient Information
4	SEC. 121. PATIENT INFORMATION.
5	(a) Disclosure Requirement.—
6	(1) GROUP HEALTH PLANS.—A group health
7	plan shall—
8	(A) provide to participants and bene-
9	ficiaries at the time of initial coverage under
10	the plan (or the effective date of this section, in
11	the case of individuals who are participants or
12	beneficiaries as of such date), and at least an-
13	nually thereafter, the information described in
14	subsection (b) in printed form;
15	(B) provide to participants and bene-
16	ficiaries, within a reasonable period (as speci-
17	fied by the appropriate Secretary) before or
18	after the date of significant changes in the in-
19	formation described in subsection (b), informa-
20	tion in printed form on such significant
21	changes; and
22	(C) upon request, make available to par-
23	ticipants and beneficiaries, the applicable au-

thority, and prospective participants and bene-

1	ficiaries, the information described in sub-
2	section (b) or (c) in printed form.
3	(2) HEALTH INSURANCE ISSUERS.—A health
4	insurance issuer in connection with the provision of
5	health insurance coverage shall—
6	(A) provide to individuals enrolled under
7	such coverage at the time of enrollment, and at
8	least annually thereafter, the information de-
9	scribed in subsection (b) in printed form;
10	(B) provide to enrollees, within a reason-
11	able period (as specified by the appropriate Sec-
12	retary) before or after the date of significant
13	changes in the information described in sub-
14	section (b), information in printed form on such
15	significant changes; and
16	(C) upon request, make available to the
17	applicable authority, to individuals who are pro-
18	spective enrollees, and to the public the infor-
19	mation described in subsection (b) or (c) in
20	printed form.
21	(b) Information Provided.—The information de-
22	scribed in this subsection with respect to a group health
23	plan or health insurance coverage offered by a health in-
24	surance issuer includes the following:

1	(1) Service area.—The service area of the
2	plan or issuer.
3	(2) Benefits.—Benefits offered under the
4	plan or coverage, including—
5	(A) covered benefits, including benefit lim-
6	its and coverage exclusions;
7	(B) cost sharing, such as deductibles, coin-
8	surance, and copayment amounts, including any
9	liability for balance billing, any maximum limi-
10	tations on out of pocket expenses, and the max-
11	imum out of pocket costs for services that are
12	provided by non participating providers or that
13	are furnished without meeting the applicable
14	utilization review requirements;
15	(C) the extent to which benefits may be ob-
16	tained from nonparticipating providers;
17	(D) the extent to which a participant, ben-
18	eficiary, or enrollee may select from among par-
19	ticipating providers and the types of providers
20	participating in the plan or issuer network;
21	(E) process for determining experimental
22	coverage; and
23	(F) use of a prescription drug formulary.
24	(3) Access.—A description of the following:

1	(A) The number, mix, and distribution of
2	providers under the plan or coverage.
3	(B) Out-of-network coverage (if any) pro-
4	vided by the plan or coverage.
5	(C) Any point-of-service option (including
6	any supplemental premium or cost-sharing for
7	such option).
8	(D) The procedures for participants, bene-
9	ficiaries, and enrollees to select, access, and
10	change participating primary and specialty pro-
11	viders.
12	(E) The rights and procedures for obtain-
13	ing referrals (including standing referrals) to
14	participating and nonparticipating providers.
15	(F) The name, address, and telephone
16	number of participating health care providers
17	and an indication of whether each such provider
18	is available to accept new patients.
19	(G) Any limitations imposed on the selec-
20	tion of qualifying participating health care pro-
21	viders, including any limitations imposed under
22	section $103(b)(2)$ .
23	(H) How the plan or issuer addresses the
24	needs of participants, beneficiaries, and enroll-
25	ees and others who do not speak English or

1 who have other special communications needs in 2 accessing providers under the plan or coverage, including the provision of information described 3 4 in this subsection and subsection (c) to such individuals and including the provision of infor-6 mation in a language other than English if 5 7 percent of the number of participants, bene-8 ficiaries, and enrollees communicate in that lan-9 guage instead of English.

- (4) Out-of-area coverage provided by the plan or issuer.
- (5) Emergency coverage of emergency services, including—
  - (A) the appropriate use of emergency services, including use of the 911 telephone system or its local equivalent in emergency situations and an explanation of what constitutes an emergency situation;
  - (B) the process and procedures of the plan or issuer for obtaining emergency services; and
  - (C) the locations of (i) emergency departments, and (ii) other settings, in which plan physicians and hospitals provide emergency services and post-stabilization care.

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- 1 (6) Percentage of Premiums used for
  2 Benefits (Loss-ratios).—In the case of health in3 surance coverage only (and not with respect to group
  4 health plans that do not provide coverage through
  5 health insurance coverage), a description of the over6 all loss-ratio for the coverage (as defined in accord7 ance with rules established or recognized by the Sec8 retary of Health and Human Services).
  - (7) Prior authorization rules.—Rules regarding prior authorization or other review requirements that could result in noncoverage or non-payment.
  - (8) Grievance and appeals procedures.—All appeal or grievance rights and procedures under the plan or coverage, including the method for filing grievances and the time frames and circumstances for acting on grievances and appeals, who is the applicable authority with respect to the plan or issuer, and the availability of assistance through an ombudsman to individuals in relation to group health plans and health insurance coverage.
  - (9) QUALITY ASSURANCE.—A summary description of the data on quality collected under section 112(a), including a summary description of the data on satisfaction of participants, beneficiaries, and en-

- rollees (including data on individual voluntary disensellment and grievances and appeals) described in section 112(b)(4).
- (10) SUMMARY OF PROVIDER FINANCIAL IN-5 CENTIVES.—A summary description of the informa-6 tion on the types of financial payment incentives 7 (described in section 1852(j)(4) of the Social Secu-8 rity Act) provided by the plan or issuer under the 9 coverage.
- 10 (11) Information on issuer.—Notice of appropriate mailing addresses and telephone numbers to be used by participants, beneficiaries, and enroll-ees in seeking information or authorization for treatment.
- 15 (12) AVAILABILITY OF INFORMATION ON RE-16 QUEST.—Notice that the information described in 17 subsection (c) is available upon request.
- 18 (c) Information Made Available Upon Re-19 Quest.—The information described in this subsection is 20 the following:
- 21 (1) Utilization review activities.—A de-22 scription of procedures used and requirements (in-23 cluding circumstances, time frames, and appeal 24 rights) under any utilization review program under

- section 115, including under any drug formulary
  program under section 107.
- 3 (2) GRIEVANCE AND APPEALS INFORMATION.—
  4 Information on the number of grievances and appeals and on the disposition in the aggregate of such
  6 matters.
  - (3) METHOD OF PHYSICIAN COMPENSATION.—
    An overall summary description as to the method of compensation of participating physicians, including information on the types of financial payment incentives (described in section 1852(j)(4) of the Social Security Act) provided by the plan or issuer under the coverage.
  - (4) Specific information on credentials of Participating provider, a description of the credentials of the provider.
  - (5) CONFIDENTIALITY POLICIES AND PROCE-DURES.—A description of the policies and procedures established to carry out section 122.
  - (6) FORMULARY RESTRICTIONS.—A description of the nature of any drug formula restrictions.
    - (7) Participating provider List.—A list of current participating health care providers.
- 25 (d) Form of Disclosure.—

- 1 (1) Uniformity.—Information required to be
  2 disclosed under this section shall be provided in ac3 cordance with uniform, national reporting standards
  4 specified by the Secretary, after consultation with
  5 applicable State authorities, so that prospective en6 rollees may compare the attributes of different
  7 issuers and coverage offered within an area.
  - (2) Information into handbook.—Nothing in this section shall be construed as preventing a group health plan or health insurance issuer from making the information under subsections (b) and (c) available to participants, beneficiaries, and enrollees through an enrollee handbook or similar publication.
    - (3) UPDATING PARTICIPATING PROVIDER INFORMATION.—The information on participating health care providers described in subsection (b)(3)(C) shall be updated within such reasonable period as determined appropriate by the Secretary. Nothing in this section shall prevent an issuer from changing or updating other information made available under this section.
- 23 (e) Construction.—Nothing in this section shall be 24 construed as requiring public disclosure of individual con-

- 1 tracts or financial arrangements between a group health
- 2 plan or health insurance issuer and any provider.

#### 3 SEC. 122. PROTECTION OF PATIENT CONFIDENTIALITY.

- 4 Insofar as a group health plan, or a health insurance
- 5 issuer that offers health insurance coverage, maintains
- 6 medical records or other health information regarding par-
- 7 ticipants, beneficiaries, and enrollees, the plan or issuer
- 8 shall establish procedures—
- 9 (1) to safeguard the privacy of any individually
- identifiable enrollee information;
- 11 (2) to maintain such records and information in
- a manner that is accurate and timely, and
- 13 (3) to assure timely access of such individuals
- to such records and information.

#### 15 SEC. 123. HEALTH INSURANCE OMBUDSMEN.

- 16 (a) IN GENERAL.—Each State that obtains a grant
- 17 under subsection (c) shall provide for creation and oper-
- 18 ation of a Health Insurance Ombudsman through a con-
- 19 tract with a not-for-profit organization that operates inde-
- 20 pendent of group health plans and health insurance
- 21 issuers. Such Ombudsman shall be responsible for at least
- 22 the following:
- (1) To assist consumers in the State in choos-
- ing among health insurance coverage or among cov-
- erage options offered within group health plans.

- 1 (2) To provide counseling and assistance to en-
- 2 rollees dissatisfied with their treatment by health in-
- 3 surance issuers and group health plans in regard to
- 4 such coverage or plans and with respect to griev-
- 5 ances and appeals regarding determinations under
- 6 such coverage or plans.
- 7 (b) Federal Role.—In the case of any State that
- 8 does not provide for such an Ombudsman under sub-
- 9 section (a), the Secretary shall provide for the creation
- 10 and operation of a Health Insurance Ombudsman through
- 11 a contract with a not-for-profit organization that operates
- 12 independent of group health plans and health insurance
- 13 issuers and that is responsible for carrying out with re-
- 14 spect to that State the functions otherwise provided under
- 15 subsection (a) by a Health Insurance Ombudsman.
- 16 (c) AUTHORIZATION OF APPROPRIATIONS.—There
- 17 are authorized to be appropriated to the Secretary of
- 18 Health and Human Services such amounts as may be nec-
- 19 essary to provide for grants to States for contracts for
- 20 Health Insurance Ombudsmen under subsection (a) or
- 21 contracts for such Ombudsmen under subsection (b).
- 22 (d) Construction.—Nothing in this section shall be
- 23 construed to prevent the use of other forms of enrollee
- 24 assistance.

# Subtitle D—Grievance and Appeals Procedures

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3	SEC	131	ESTARI	ISHMENT	OF (	GRIEVA	NCE	PROCESS	

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- (a) Establishment of Grievance System.—
- (1) IN GENERAL.—A group health plan, and a 5 6 health insurance issuer in connection with the provi-7 sion of health insurance coverage, shall establish and 8 maintain a system to provide for the presentation 9 and resolution of oral and written grievances 10 brought by individuals who are participants, bene-11 ficiaries, or enrollees, or health care providers or 12 other individuals acting on behalf of an individual 13 and with the individual's consent, regarding any as-14 pect of the plan's or issuer's services.
  - (2) Scope.—The system shall include grievances regarding access to and availability of services, quality of care, choice and accessibility of providers, network adequacy, and compliance with the requirements of this title.
- 20 (b) GRIEVANCE SYSTEM.—Such system shall include 21 the following components with respect to individuals who 22 are participants, beneficiaries, or enrollees:
- 23 (1) Written notification to all such individuals 24 and providers of the telephone numbers and business

- addresses of the plan or issuer personnel responsible
  for resolution of grievances and appeals.
- 3 (2) A system to record and document, over a 4 period of at least 3 previous years, all grievances 5 and appeals made and their status.
- (3) A process providing for timely processing
   and resolution of grievances.
  - (4) Procedures for follow-up action, including the methods to inform the person making the grievance of the resolution of the grievance.
- 11 (5) Notification to the continuous quality im-12 provement program under section 111(a) of all 13 grievances and appeals relating to quality of care.
- 14 SEC. 132. INTERNAL APPEALS OF ADVERSE DETERMINA-
- 15 TIONS.

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- 16 (a) RIGHT OF APPEAL.—
- 17 (1) In General.—A participant or beneficiary 18 in a group health plan, and an enrollee in health in-19 surance coverage offered by a health insurance 20 issuer, and any provider or other person acting on 21 behalf of such an individual with the individual's 22 consent, may appeal any appealable decision (as de-23 fined in paragraph (2)) under the procedures de-24 scribed in this section and (to the extent applicable) 25 section 133. Such individuals and providers shall be

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1	provided with a written explanation of the appeal
2	process and the determination upon the conclusion
3	of the appeals process and as provided in section
4	121(b)(8).
5	(2) Appealable decision defined.—In this
6	section, the term "appealable decision" means any of
7	the following:
8	(A) Denial, reduction, or termination of, or
9	failure to provide or make payment (in whole or
10	in part) for, a benefit, including a failure to
11	cover an item or service for which benefits are
12	otherwise provided because it is determined to
13	be experimental or investigational or not medi-
14	cally necessary or appropriate.
15	(B) Failure to provide coverage of emer-
16	gency services or reimbursement of mainte-
17	nance care or post-stabilization care under sec-
18	tion 101.
19	(C) Failure to provide a choice of provider
20	under section 103.
21	(D) Failure to provide qualified health care

providers under section 103.

and other care under section 104.

(E) Failure to provide access to specialty

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1	(F) Failure to provide continuation of care
2	under section 105.
3	(G) Failure to provide coverage of routine
4	patient costs in connection with an approval
5	clinical trial under section 106.
6	(H) Failure to provide access to needed
7	drugs under section $107(a)(3)$ or $107(b)$ .
8	(I) Discrimination in delivery of services in
9	violation of section 109.
10	(J) An adverse determination under a utili-
11	zation review program under section 115.
12	(K) The imposition of a limitation that is
13	prohibited under section 151.
14	(b) Internal Appeal Process.—
15	(1) In general.—Each group health plan and
16	health insurance issuer shall establish and maintain
17	an internal appeal process under which any partici-
18	pant, beneficiary, enrollee, or provider acting on be-
19	half of such an individual with the individual's con-
20	sent, who is dissatisfied with any appealable decision
21	has the opportunity to appeal the decision through
22	an internal appeal process. The appeal may be com-
23	municated orally.
24	(2) Conduct of Review.—

1	(A) In General.—The process shall in
2	clude a review of the decision by a physician or
3	other health care professional (or professionals)
4	who has been selected by the plan or issuer and
5	who has not been involved in the appealable de
6	cision at issue in the appeal.
7	(B) AVAILABILITY AND PARTICIPATION OF
8	CLINICAL PEERS.—The individuals conducting
9	such review shall include one or more clinica
10	peers (as defined in section 191(c)(2)) who have
11	not been involved in the appealable decision as
12	issue in the appeal.
13	(3) Deadline.—
14	(A) In general.—Subject to subsection
15	(c), the plan or issuer shall conclude each ap-
16	peal as soon as possible after the time of the re-
17	ceipt of the appeal in accordance with medica
18	exigencies of the case involved, but in no even
19	later than—
20	(i) 72 hours after the time of receipt
21	of an expedited appeal, and
22	(ii) except as provided in subpara-
23	graph (B), 15 business days after such

time in the case of all other appeals.

- 1 (B) EXTENSION.—A group health plan or health insurance issuer may extend the deadline 2 3 for an appeal that does not relate to a decision 4 regarding an expedited appeal and that does 5 not involve medical exigencies up to an addi-6 tional 10 business days where it can dem-7 onstrate to the applicable authority reasonable 8 cause for the delay beyond its control and 9 where it provides, within the original deadline 10 under subparagraph (A), a written progress report and explanation for the delay to such au-12 thority and to the participant, beneficiary, or 13 enrollee and provider involved.
  - (4) Notice.—If a plan or issuer denies an appeal, the plan or issuer shall provide the participant, beneficiary, or enrollee and provider involved with notice in printed form of the denial and the reasons therefore, together with a notice in printed form of rights to any further appeal.

# (c) Expedited Review Process.—

(1) IN GENERAL.—A group health plan, and a health insurance issuer, shall establish procedures in writing for the expedited consideration of appeals under subsection (b) in situations in which the application of the normal timeframe for making a deter-

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mination could seriously jeopardize the life or health of the participant, beneficiary, or enrollee or such an individual's ability to regain maximum function.

# (2) Process.—Under such procedures—

- (A) the request for expedited appeal may be submitted orally or in writing by an individual or provider who is otherwise entitled to request the appeal;
- (B) all necessary information, including the plan's or issuer's decision, shall be transmitted between the plan or issuer and the requester by telephone, facsimile, or other similarly expeditious available method; and
- (C) the plan or issuer shall expedite the appeal if the request for an expedited appeal is submitted under subparagraph (A) by a physician and the request indicates that the situation described in paragraph (1) exists.
- 19 (d) DIRECT USE OF FURTHER APPEALS.—In the 20 event that the plan or issuer fails to comply with any of 21 the deadlines for completion of appeals under this section 22 or in the event that the plan or issuer for any reason ex-23 pressly waives its rights to an internal review of an appeal 24 under subsection (b), the participant, beneficiary, or en-25 rollee involved and the provider involved shall be relieved

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1	of any obligation to complete the appeal involved and may
2	at such an individual's or provider's option, proceed di-
3	rectly to seek further appeal through any applicable exter-
4	nal appeals process.
5	SEC. 133. EXTERNAL APPEALS OF ADVERSE DETERMINA
6	TIONS.
7	(a) RIGHT TO EXTERNAL APPEAL.—
8	(1) In general.—A group health plan, and a
9	health insurance issuer offering group health insur-
10	ance coverage, shall provide for an external appeals
11	process that meets the requirements of this section
12	in the case of an externally appealable decision de-
13	scribed in paragraph (2). The appropriate Secretary
14	shall establish standards to carry out such require-
15	ments.
16	(2) Externally appealable decision de-
17	FINED.—For purposes of this section, the term "ex-
18	ternally appealable decision" means an appealable
19	decision (as defined in section 132(a)(2)) if—
20	(A) the amount involved exceeds a signifi-
21	cant threshold; or
22	(B) the patient's life or health is jeopard-
23	ized as a consequence of the decision.

1	Such term does not include a denial of coverage for
2	services that are specifically listed in plan or cov-
3	erage documents as excluded from coverage.
4	(3) Exhaustion of internal appeals proc-
5	Ess.—A plan or issuer may condition the use of an
6	external appeal process in the case of an externally
7	appealable decision upon completion of the internal
8	review process provided under section 132, but only
9	if the decision is made in a timely basis consistent
10	with the deadlines provided under this subtitle.
11	(b) General Elements of External Appeals
12	Process.—
13	(1) Contract with qualified external ap-
14	PEAL ENTITY.—
15	(A) Contract requirement.—Subject to
16	subparagraph (B), the external appeal process
17	under this section of a plan or issuer shall be
18	conducted under a contract between the plan or
19	issuer and one or more qualified external appeal
20	entities (as defined in subsection (c)).
21	(B) Restrictions on qualified exter-
22	NAL APPEAL ENTITY.—
23	(i) By state for health insur-
24	ANCE ISSUERS.—With respect to health in-
25	surance issuers in a State, the State may

1	provide for external review activities to be
2	conducted by a qualified external appeal
3	entity that is designated by the State or
4	that is selected by the State in such a
5	manner as to assure an unbiased deter-
6	mination.
7	(ii) By federal government for
8	GROUP HEALTH PLANS.—With respect to
9	group health plans, the appropriate Sec-
10	retary may exercise the same authority as
11	a State may exercise with respect to health
12	insurance issuers under clause (i). Such
13	authority may include requiring the use of
14	the qualified external appeal entity des-
15	ignated or selected under such clause.
16	(iii) Limitation on plan or issuer
17	SELECTION.—If an applicable authority
18	permits more than one entity to qualify as
19	a qualified external appeal entity with re-
20	spect to a group health plan or health in-
21	surance issuer and the plan or issuer may
22	select among such qualified entities, the
23	applicable authority—
24	(I) shall assure that the selection
25	process will not create any incentives

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1	for external appeal entities to make a
2	decision in a biased manner, and
3	(II) shall implement procedures
4	for auditing a sample of decisions by
5	such entities to assure that no such
6	decisions are made in a biased man-
7	ner.
8	(C) OTHER TERMS AND CONDITIONS.—
9	The terms and conditions of a contract under
10	this paragraph shall be consistent with the
11	standards the appropriate Secretary shall estab-
12	lish to assure there is no real or apparent con-
13	flict of interest in the conduct of external ap-
14	peal activities. Such contract shall provide that
15	the direct costs of the process (not including
16	costs of representation of a participant, bene-
17	ficiary, or enrollee) shall be paid by the plan or
18	issuer, and not by the participant, beneficiary,
19	or enrollee.
20	(2) Elements of Process.—An external ap-
21	peal process shall be conducted consistent with

standards established by the appropriate Secretary

that include at least the following:

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1	(A) Fair process; de novo determina-
2	TION.—The process shall provide for a fair, de
3	novo determination.
4	(B) Determination concerning exter-
5	NALLY APPEALABLE DECISIONS.—A qualified
6	external appeal entity shall determine whether a
7	decision is an externally appealable decision and
8	related decisions, including—
9	(i) whether such a decision involves an
10	expedited appeal;
11	(ii) the appropriate deadlines for in-
12	ternal review process required due to medi-
13	cal exigencies in a case; and
14	(iii) whether such a process has been
15	completed.
16	(C) Opportunity to submit evidence,
17	HAVE REPRESENTATION, AND MAKE ORAL
18	PRESENTATION.—Each party to an externally
19	appealable decision—
20	(i) may submit and review evidence
21	related to the issues in dispute,
22	(ii) may use the assistance or rep-
23	resentation of one or more individuals (any
24	of whom may be an attorney), and
25	(iii) may make an oral presentation.

1	(D) Provision of Information.—The
2	plan or issuer involved shall provide timely ac-
3	cess to all its records relating to the matter of
4	the externally appealable decision and to all
5	provisions of the plan or health insurance cov-
6	erage (including any coverage manual) relating
7	to the matter.
8	(E) Timely decisions.—A determination
9	by the external appeal entity on the decision
10	shall—
11	(i) be made orally or in writing and,
12	if it is made orally, shall be supplied to the
13	parties in writing as soon as possible;
14	(ii) be binding on the plan or issuer;
15	(iii) be made in accordance with the
16	medical exigencies of the case involved, but
17	in no event later than 60 days (or 72
18	hours in the case of an expedited appeal)
19	from the date of completion of the filing of
20	notice of external appeal of the decision;
21	(iv) state, in layperson's language, the
22	basis for the determination, including, if
23	relevant, any basis in the terms or condi-
24	tions of the plan or coverage; and

1	(v) inform the participant, beneficiary,
2	or enrollee of the individual's rights to seek
3	further review by the courts (or other proc-
4	ess) of the external appeal determination.
5	(c) Qualifications of External Appeal Enti-
6	TIES.—
7	(1) In general.—For purposes of this section,
8	the term "qualified external appeal entity" means,
9	in relation to a plan or issuer, an entity (which may
10	be a governmental entity) that is certified under
11	paragraph (2) as meeting the following require-
12	ments:
13	(A) There is no real or apparent conflict of
14	interest that would impede the entity conduct-
15	ing external appeal activities independent of the
16	plan or issuer.
17	(B) The entity conducts external appeal
18	activities through clinical peers.
19	(C) The entity has sufficient medical, legal,
20	and other expertise and sufficient staffing to
21	conduct external appeal activities for the plan
22	or issuer on a timely basis consistent with sub-
23	section $(b)(3)(E)$ .

1	(D) The entity meets such other require-
2	ments as the appropriate Secretary may im-
3	pose.
4	(2) Certification of external appeal en-
5	TITIES.—
6	(A) IN GENERAL.—In order to be treated
7	as a qualified external appeal entity with re-
8	spect to—
9	(i) a group health plan, the entity
10	must be certified (and, in accordance with
11	subparagraph (B), periodically recertified)
12	as meeting the requirements of paragraph
13	(1) by the Secretary of Labor (or under a
14	process recognized or approved by the Sec-
15	retary of Labor); or
16	(ii) a health insurance issuer operat-
17	ing in a State, the entity must be certified
18	(and, in accordance with subparagraph
19	(B), periodically recertified) as meeting
20	such requirements by the applicable State
21	authority (or, if the States has not estab-
22	lished an adequate certification and recer-
23	tification process, by the Secretary of
24	Health and Human Services, or under a

1	process recognized or approved by such
2	Secretary).
3	(B) RECERTIFICATION PROCESS.—The ap-
4	propriate Secretary shall develop standards for
5	the recertification of external appeal entities.
6	Such standards shall include a specification
7	of—
8	(i) the information required to be sub-
9	mitted as a condition of recertification on
10	the entity's performance of external appeal
11	activities, which information shall include
12	the number of cases reviewed, a summary
13	of the disposition of those cases, the length
14	of time in making determinations on those
15	cases, and such information as may be nec-
16	essary to assure the independence of the
17	entity from the plans or issuers for which
18	external appeal activities are being con-
19	ducted; and
20	(ii) the periodicity which recertifi-
21	cation will be required.
22	(d) Continuing Legal Rights of Enrollees.—
23	Nothing in this title shall be construed as removing any
24	legal rights of participants, beneficiaries, enrollees, and

1	others under State or Federal law, including the right to
2	file judicial actions to enforce rights.
3	Subtitle E—Protecting the Doctor-
4	Patient Relationship
5	SEC. 141. PROHIBITION OF INTERFERENCE WITH CERTAIN
6	MEDICAL COMMUNICATIONS.
7	(a) Prohibition.—
8	(1) General Rule.—The provisions of any
9	contract or agreement, or the operation of any con-
10	tract or agreement, between a group health plan or
11	health insurance issuer in relation to health insur-
12	ance coverage (including any partnership, associa-
13	tion, or other organization that enters into or ad-
14	ministers such a contract or agreement) and a
15	health care provider (or group of health care provid-
16	ers) shall not prohibit or restrict the provider from
17	engaging in medical communications with the pro-
18	vider's patient.
19	(2) Nullification.—Any contract provision or
20	agreement described in paragraph (1) shall be null
21	and void.
22	(b) Rules of Construction.—Nothing in this sec-
23	tion shall be construed—
24	(1) to prohibit the enforcement, as part of a
25	contract or agreement to which a health care pro-

1 vider is a party, of any mutually agreed upon terms 2 and conditions, including terms and conditions re-3 quiring a health care provider to participate in, and cooperate with, all programs, policies, and proce-5 dures developed or operated by a group health plan 6 or health insurance issuer to assure, review, or im-7 prove the quality and effective utilization of health 8 care services (if such utilization is according to 9 guidelines or protocols that are based on clinical or 10 scientific evidence and the professional judgment of the provider) but only if the guidelines or protocols 12 under such utilization do not prohibit or restrict 13 medical communications between providers and their 14 patients; or

- (2) to permit a health care provider to misrepresent the scope of benefits covered under the group health plan or health insurance coverage or to otherwise require a group health plan health insurance issuer to reimburse providers for benefits not covered under the plan or coverage.
- 21 (c) Medical Communication Defined.—In this 22 section:
- 23 (1) IN GENERAL.—The term "medical communication" means any communication made by a 24 25 health care provider with a patient of the health care

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1	provider (or the guardian or legal representative of
2	such patient) with respect to—
3	(A) the patient's health status, medical
4	care, or treatment options;
5	(B) any utilization review requirements
6	that may affect treatment options for the pa-
7	tient; or
8	(C) any financial incentives that may af-
9	fect the treatment of the patient.
10	(2) Misrepresentation.—The term "medical
11	communication" does not include a communication
12	by a health care provider with a patient of the
13	health care provider (or the guardian or legal rep-
14	resentative of such patient) if the communication in-
15	volves a knowing or willful misrepresentation by
16	such provider.
17	SEC. 142. PROHIBITION AGAINST TRANSFER OF INDEM-
18	NIFICATION OR IMPROPER INCENTIVE AR-
19	RANGEMENTS.
20	(a) Prohibition of Transfer of Indemnifica-
21	TION.—
22	(1) In general.—No contract or agreement
23	between a group health plan or health insurance
24	issuer (or any agent acting on behalf of such a plan
25	or issuer) and a health care provider shall contain

- 1 any provision purporting to transfer to the health
- 2 care provider by indemnification or otherwise any li-
- ability relating to activities, actions, or omissions of
- 4 the plan, issuer, or agent (as opposed to the pro-
- 5 vider).
- 6 (2) Nullification.—Any contract or agree-
- 7 ment provision described in paragraph (1) shall be
- 8 null and void.
- 9 (b) Prohibition of Improper Physician Incen-
- 10 TIVE PLANS.—
- 11 (1) IN GENERAL.—A group health plan and a
- health insurance issuer offering health insurance
- 13 coverage may not operate any physician incentive
- plan (as defined in subparagraph (B) of section
- 15 1876(i)(8) of the Social Security Act) unless the re-
- quirements described in subparagraph (A) of such
- section are met with respect to such a plan.
- 18 (2) Application.—For purposes of carrying
- out paragraph (1), any reference in section
- 20 1876(i)(8) of the Social Security Act to the Sec-
- 21 retary, an eligible organization, or an individual en-
- rolled with the organization shall be treated as a ref-
- erence to the applicable authority, a group health
- plan or health insurance issuer, respectively, and a

1	participant, beneficiary, or enrollee with the plan or
2	organization, respectively.
3	SEC. 143. ADDITIONAL RULES REGARDING PARTICIPATION
4	OF HEALTH CARE PROFESSIONALS.
5	(a) Procedures.—Insofar as a group health plan,
6	or health insurance issuer that offers health insurance cov-
7	erage, provides benefits through participating health care
8	professionals, the plan or issuer shall establish reasonable
9	procedures relating to the participation (under an agree-
10	ment between a professional and the plan or issuer) of
11	such professionals under the plan or coverage. Such proce-
12	dures shall include—
13	(1) providing notice of the rules regarding par-
14	ticipation;
15	(2) providing written notice of participation de-
16	cisions that are adverse to professionals; and
17	(3) providing a process within the plan or issuer
18	for appealing such adverse decisions, including the
19	presentation of information and views of the profes-
20	sional regarding such decision.
21	(b) Consultation in Medical Policies.—A group
22	health plan, and health insurance issuer that offers health
23	insurance coverage, shall consult with participating physi-
24	cians (if any) regarding the plan's or issuer's medical pol-
25	icy, quality, and medical management procedures.

## 1 SEC. 144. PROTECTION FOR PATIENT ADVOCACY.

2	(a) Protection for Use of Utilization Review
3	AND GRIEVANCE PROCESS.—A group health plan, and a
4	health insurance issuer with respect to the provision of
5	health insurance coverage, may not retaliate against a par-
6	ticipant, beneficiary, enrollee, or health care provider
7	based on the participant's, beneficiary's, enrollee's or pro-
8	vider's use of, or participation in, a utilization review proc-
9	ess or a grievance process of the plan or issuer (including
10	an internal or external review or appeal process) under
11	this title.
12	(b) Protection for Quality Advocacy by
13	HEALTH CARE PROFESSIONALS.—
14	(1) In general.—A group health plan or
15	health insurance issuer may not retaliate or dis-
16	criminate against a protected health care profes-
17	sional because the professional in good faith—
18	(A) discloses information relating to the
19	care, services, or conditions affecting one or
20	more participants, beneficiaries, or enrollees of
21	the plan or issuer to an appropriate public reg-
22	ulatory agency, an appropriate private accredi-
23	tation body, or appropriate management per-
24	sonnel of the plan or issuer; or
25	(B) initiates, cooperates, or otherwise par-
26	ticipates in an investigation or proceeding by

such an agency with respect to such care, services, or conditions.

If an institutional health care provider is a participating provider with such a plan or issuer or otherwise receives payments for benefits provided by such a plan or issuer, the provisions of the previous sentence shall apply to the provider in relation to care, services, or conditions affecting one or more patients within an institutional health care provider in the same manner as they apply to the plan or issuer in relation to care, services, or conditions provided to one or more participants, beneficiaries, or enrollees; and for purposes of applying this sentence, any reference to a plan or issuer is deemed a reference to the institutional health care provider.

- (2) Good faith action.—For purposes of paragraph (1), a protected health care professional is considered to be acting in good faith with respect to disclosure of information or participation if, with respect to the information disclosed as part of the action—
  - (A) the disclosure is made on the basis of personal knowledge and is consistent with that degree of learning and skill ordinarily possessed by health care professionals with the same li-

1	censure or certification and the same experi-
2	ence;
3	(B) the professional reasonably believes the
4	information to be true;
5	(C) the information evidences either a vio-
6	lation of a law, rule, or regulation, of an appli-
7	cable accreditation standard, or of a generally
8	recognized professional or clinical standard or
9	that a patient is in imminent hazard of loss of
10	life or serious injury; and
11	(D) subject to subparagraphs (B) and (C)
12	of paragraph (3), the professional has followed
13	reasonable internal procedures of the plan,
14	issuer, or institutional health care provider es-
15	tablished or the purpose of addressing quality
16	concerns before making the disclosure.
17	(3) Exception and special rule.—
18	(A) General exception.—Paragraph (1)
19	does not protect disclosures that would violate
20	Federal or State law or diminish or impair the
21	rights of any person to the continued protection
22	of confidentiality of communications provided
23	by such law.
24	(B) Notice of internal procedures.—
25	Subparagraph (D) of paragraph (2) shall not

1 apply unless the internal procedures involved 2 are reasonably expected to be known to the 3 health care professional involved. For purposes of this subparagraph, a health care professional is reasonably expected to know of internal pro-6 cedures if those procedures have been made 7 available to the professional through distribu-8 tion or posting. 9 (C) Internal procedure exception.— 10 Subparagraph (D) of paragraph (2) also shall 11 not apply if— 12 (i) the disclosure relates to an immi-13 nent hazard of loss of life or serious injury 14 to a patient; 15 (ii) the disclosure is made to an ap-16 propriate private accreditation body pursu-17 ant to disclosure procedures established by 18 the body; or 19 (iii) the disclosure is in response to an 20 inquiry made in an investigation or pro-21 ceeding of an appropriate public regulatory 22 agency and the information disclosed is 23 limited to the scope of the investigation or

proceeding.

- (4) Additional considerations.—It shall not be a violation of paragraph (1) to take an adverse action against a protected health care professional if the plan, issuer, or provider taking the adverse action involved demonstrates that it would have taken the same adverse action even in the absence of the activities protected under such paragraph.
  - (5) Notice.—A group health plan, health insurance issuer, and institutional health care provider shall post a notice, to be provided or approved by the Secretary of Labor, setting forth excerpts from, or summaries of, the pertinent provisions of this subsection and information pertaining to enforcement of such provisions.

#### (6) Constructions.—

- (A) DETERMINATIONS OF COVERAGE.—
  Nothing in this subsection shall be construed to prohibit a plan or issuer from making a determination not to pay for a particular medical treatment or service or the services of a type of health care professional.
- (B) Enforcement of Peer Review Protocols and internal procedures.—Nothing in this subsection shall be construed to pro-

- hibit a plan, issuer, or provider from establishing and enforcing reasonable peer review or utilization review protocols or determining whether a protected health care professional has complied with those protocols or from establishing and enforcing internal procedures for the purpose of addressing quality concerns.
  - (C) Relation to other rights.—Nothing in this subsection shall be construed to abridge rights of participants, beneficiaries, enrollees, and protected health care professionals under other applicable Federal or State laws.
  - (7) Protected health care professional Defined.—For purposes of this subsection, the term "protected health care professional" means an individual who is a licensed or certified health care professional and who—
    - (A) with respect to a group health plan or health insurance issuer, is an employee of the plan or issuer or has a contract with the plan or issuer for provision of services for which benefits are available under the plan or issuer; or
    - (B) with respect to an institutional health care provider, is an employee of the provider or has a contract or other arrangement with the

1	provider respecting the provision of health care
2	services.
3	Subtitle F—Promoting Good
4	<b>Medical Practice</b>
5	SEC. 151. PROMOTING GOOD MEDICAL PRACTICE.
6	(a) Prohibiting Arbitrary Limitations or Con-
7	DITIONS FOR THE PROVISION OF SERVICES.—
8	(1) IN GENERAL.—A group health plan, and a
9	health insurance issuer in connection with the provi-
10	sion of health insurance coverage, may not arbitrar-
11	ily interfere with or alter the decision of the treating
12	physician regarding the manner or setting in which
13	particular services are delivered if the services are
14	medically necessary or appropriate for treatment or
15	diagnosis to the extent that such treatment or diag-
16	nosis is otherwise a covered benefit.
17	(2) Construction.—Paragraph (1) shall not
18	be construed as prohibiting a plan or issuer from
19	limiting the delivery of services to one or more
20	health care providers within a network of such pro-
21	viders.
22	(b) No Change in Coverage.—Subsection (a) shall
23	not be construed as requiring coverage of particular serv-
24	ices the coverage of which is otherwise not covered under

1	the terms of the plan or coverage or from conducting utili-
2	zation review activities consistent with this subsection.
3	(c) Medical Necessity or Appropriateness De-
4	FINED.—In subsection (a), the term "medically necessary
5	or appropriate" means, with respect to a service or benefit,
6	a service or benefit which is consistent with generally ac-
7	cepted principles of professional medical practice.
8	SEC. 152. STANDARDS RELATING TO BENEFITS FOR CER-
9	TAIN BREAST CANCER TREATMENT.
10	(a) Requirements for Minimum Hospital Stay
11	FOLLOWING MASTECTOMY OR LYMPH NODE DISSEC-
12	TION.—
13	(1) IN GENERAL.—A group health plan, and a
14	health insurance issuer offering group health insur-
15	ance coverage, may not—
16	(A) except as provided in paragraph (2)—
17	(i) restrict benefits for any hospital
18	length of stay in connection with a mastec-
19	tomy for the treatment of breast cancer to
20	less than 48 hours, or
21	(ii) restrict benefits for any hospital
22	length of stay in connection with a lymph
23	node dissection for the treatment of breast
24	cancer to less than 24 hours, or

- 1 (B) require that a provider obtain author-2 ization from the plan or the issuer for prescrib-3 ing any length of stay required under subpara-4 graph (A) (without regard to paragraph (2)).
- 5 (2) Exception.—Paragraph (1)(A) shall not 6 apply in connection with any group health plan or health insurance issuer in any case in which the de-7 8 cision to discharge the woman involved prior to the 9 expiration of the minimum length of stay otherwise 10 required under paragraph (1)(A) is made by the at-11 tending provider in consultation with the woman or 12 in a case involving a partial mastectomy without 13 lymph node dissection.
- 14 (b) Prohibitions.—A group health plan, and a
  15 health insurance issuer offering group health insurance
  16 coverage in connection with a group health plan, may
  17 not—
  - (1) deny to a woman eligibility, or continued eligibility, to enroll or to renew coverage under the terms of the plan, solely for the purpose of avoiding the requirements of this section;
  - (2) provide monetary payments or rebates to women to encourage such women to accept less than the minimum protections available under this section:

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1	(3) penalize or otherwise reduce or limit the re
2	imbursement of an attending provider because such
3	provider provided care to an individual participan
4	or beneficiary in accordance with this section;
5	(4) provide incentives (monetary or otherwise
6	to an attending provider to induce such provider to
7	provide care to an individual participant or bene
8	ficiary in a manner inconsistent with this section; or
9	(5) subject to subsection (c)(3), restrict benefits
10	for any portion of a period within a hospital length
11	of stay required under subsection (a) in a manner
12	which is less favorable than the benefits provided for
13	any preceding portion of such stay.
14	(c) Rules of Construction.—
15	(1) Nothing in this section shall be construed to
16	require a woman who is a participant or bene
17	ficiary—
18	(A) to undergo a mastectomy or lymph
19	node dissection in a hospital; or
20	(B) to stay in the hospital for a fixed pe
21	riod of time following a mastectomy or lymph
22	node dissection.
23	(2) This section shall not apply with respect to
24	any group health plan, or any group health insur

ance coverage offered by a health insurance issuer,

- which does not provide benefits for hospital lengths
  of stay in connection with a mastectomy or lymph
  node dissection for the treatment of breast cancer.
- (3) Nothing in this section shall be construed as 5 preventing a group health plan or issuer from impos-6 ing deductibles, coinsurance, or other cost-sharing in 7 relation to benefits for hospital lengths of stay in 8 connection with a mastectomy or lymph node dissec-9 tion for the treatment of breast cancer under the 10 plan (or under health insurance coverage offered in 11 connection with a group health plan), except that 12 such coinsurance or other cost-sharing for any por-13 tion of a period within a hospital length of stay re-14 quired under subsection (a) may not be greater than 15 such coinsurance or cost-sharing for any preceding 16 portion of such stay.
- 17 (d) Level and Type of Reimbursements.—Noth-
- 18 ing in this section shall be construed to prevent a group
- 19 health plan or a health insurance issuer offering group
- 20 health insurance coverage from negotiating the level and
- 21 type of reimbursement with a provider for care provided
- 22 in accordance with this section.
- (e) Exception for Health Insurance Coverage
- 24 IN CERTAIN STATES.—

- 1 (1) IN GENERAL.—The requirements of this 2 section shall not apply with respect to health insur-3 ance coverage if there is a State law (as defined in 4 section 2723(d)(1) of the Public Health Service Act) 5 for a State that regulates such coverage that is de-6 scribed in any of the following subparagraphs:
  - (A) Such State law requires such coverage to provide for at least a 48-hour hospital length of stay following a mastectomy performed for treatment of breast cancer and at least a 24-hour hospital length of stay following a lymph node dissection for treatment of breast cancer.
  - (B) Such State law requires, in connection with such coverage for surgical treatment of breast cancer, that the hospital length of stay for such care is left to the decision of (or required to be made by) the attending provider in consultation with the woman involved.
  - (2) Construction.—Section 2723(a)(1) of the Public Health Service Act and section 731(a)(1) of the Employee Retirement Income Security Act of 1974 shall not be construed as superseding a State law described in paragraph (1).

### SEC. 153. STANDARDS RELATING TO BENEFITS FOR RECON-

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,	2 STRUCTIVE	DDEACT	CIIDCEDV
/		DDCASI	SUBSTRA.I.

- 3 (a) Requirements for Reconstructive Breast4 Surgery.—
- 5 (1) IN GENERAL.—A group health plan, and a 6 health insurance issuer offering group health insur-7 ance coverage, that provides coverage for breast sur-8 gery in connection with a mastectomy shall provide 9 coverage for reconstructive breast surgery resulting 10 from the mastectomy. Such coverage shall include 11 coverage for all stages of reconstructive breast surgery performed on a nondiseased breast to establish 12 13 symmetry with the diseased when reconstruction on 14 the diseased breast is performed and coverage of 15 prostheses and complications of mastectomy includ-16 ing lymphedema.
  - (2) Reconstructive breast surgery defined.—In this section, the term "reconstructive breast surgery" means surgery performed as a result of a mastectomy to reestablish symmetry between two breasts, and includes augmentation mammoplasty, reduction mammoplasty, and mastopexy.
- 24 (3) Mastectomy defined.—In this section, 25 the term "mastectomy" means the surgical removal 26 of all or part of a breast.

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## (b) Prohibitions.—

- (1) Denial of Coverage based on Cosmetic surgery.—A group health plan, and a health insurance issuer offering group health insurance coverage in connection with a group health plan, may not deny coverage described in subsection (a)(1) on the basis that the coverage is for cosmetic surgery.
- (2) APPLICATION OF SIMILAR PROHIBITIONS.— Paragraphs (2) through (5) of section 152 shall apply under this section in the same manner as they apply with respect to section 152.

## (c) Rules of Construction.—

- (1) Nothing in this section shall be construed to require a woman who is a participant or beneficiary to undergo reconstructive breast surgery.
- (2) This section shall not apply with respect to any group health plan, or any group health insurance coverage offered by a health insurance issuer, which does not provide benefits for mastectomies.
- (3) Nothing in this section shall be construed as preventing a group health plan or issuer from imposing deductibles, coinsurance, or other cost-sharing in relation to benefits for reconstructive breast surgery under the plan (or under health insurance coverage offered in connection with a group health plan), ex-

- 1 cept that such coinsurance or other cost-sharing for
- 2 any portion may not be greater than such coinsur-
- ance or cost-sharing that is otherwise applicable with
- 4 respect to benefits for mastectomies.
- 5 (e) Level and Type of Reimbursements.—Noth-
- 6 ing in this section shall be construed to prevent a group
- 7 health plan or a health insurance issuer offering group
- 8 health insurance coverage from negotiating the level and
- 9 type of reimbursement with a provider for care provided
- 10 in accordance with this section.
- 11 (f) Exception for Health Insurance Coverage
- 12 IN CERTAIN STATES.—
- 13 (1) In General.—The requirements of this
- section shall not apply with respect to health insur-
- ance coverage if there is a State law (as defined in
- section 2723(d)(1) of the Public Health Service Act)
- for a State that regulates such coverage and that re-
- quires coverage of at least the coverage of recon-
- 19 structive breast surgery otherwise required under
- this section.
- 21 (2) Construction.—Section 2723(a)(1) of the
- Public Health Service Act and section 731(a)(1) of
- 23 the Employee Retirement Income Security Act of
- 24 1974 shall not be construed as superseding a State
- law described in paragraph (1).

# Subtitle G—Definitions

#### 2 SEC. 191. DEFINITIONS.

- 3 (a) Incorporation of General Definitions.—
- 4 The provisions of section 2971 of the Public Health Serv-
- 5 ice Act shall apply for purposes of this title in the same
- 6 manner as they apply for purposes of title XXVII of such
- 7 Act.

- 8 (b) Secretary.—Except as otherwise provided, the
- 9 term "Secretary" means the Secretary of Health and
- 10 Human Services, in consultation with the Secretary of
- 11 Labor and the Secretary of the Treasury and the term
- 12 "appropriate Secretary" means the Secretary of Health
- 13 and Human Services in relation to carrying out this title
- 14 under sections 2706 and 2751 of the Public Health Serv-
- 15 ice Act, the Secretary of Labor in relation to carrying out
- 16 this title under section 713 of the Employee Retirement
- 17 Income Security Act of 1974, and the Secretary of the
- 18 Treasury in relation to carrying out this title under chap-
- 19 ter 100 and section 4980D of the Internal Revenue Code
- 20 of 1986.
- 21 (c) Additional Definitions.—For purposes of this
- 22 title:
- 23 (1) Applicable authority.—The term "ap-
- 24 plicable authority" means—

- 1 (A) in the case of a group health plan, the 2 Secretary of Health and Human Services and 3 the Secretary of Labor; and
  - (B) in the case of a health insurance issuer with respect to a specific provision of this title, the applicable State authority (as defined in section 2791(d) of the Public Health Service Act), or the Secretary of Health and Human Services, if such Secretary is enforcing such provision under section 2722(a)(2) or 2761(a)(2) of the Public Health Service Act.
  - (2) CLINICAL PEER.—The term "clinical peer" means, with respect to a review or appeal, a physician (allopathic or osteopathic) or other health care professional who holds a non-restricted license in a State and who is appropriately credentialed in the same or similar specialty as typically manages the medical condition, procedure, or treatment under review or appeal and includes a pediatric specialist where appropriate; except that only a physician may be a clinical peer with respect to the review or appeal of treatment rendered by a physician.
  - (3) HEALTH CARE PROVIDER.—The term "health care provider" includes a physician or other

- health care professional, as well as an institutional
  provider of health care services.
- 3 (4) Nonparticipating.—The term "non4 participating" means, with respect to a health care
  5 provider that provides health care items and services
  6 to a participant, beneficiary, or enrollee under group
  7 health plan or health insurance coverage, a health
  8 care provider that is not a participating health care
  9 provider with respect to such items and services.
- 10 (5) Participating.—The term "participating" 11 mean, with respect to a health care provider that 12 provides health care items and services to a partici-13 pant, beneficiary, or enrollee under group health 14 plan or health insurance coverage offered by a 15 health insurance issuer, a health care provider that 16 furnishes such items and services under a contract 17 or other arrangement with the plan or issuer.
- 18 SEC. 192. PREEMPTION; STATE FLEXIBILITY; CONSTRUC-19 TION.
- 20 (a) Continued Applicability of State Law 21 With Respect to Health Insurance Issuers.—
- 22 (1) IN GENERAL.—Subject to paragraph (2), 23 this title shall not be construed to supersede any 24 provision of State law which establishes, implements, 25 or continues in effect any standard or requirement

- 1 solely relating to health insurance issuers in connec-
- 2 tion with group health insurance coverage except to
- 3 the extent that such standard or requirement pre-
- 4 vents the application of a requirement of this title.
- 5 (2) CONTINUED PREEMPTION WITH RESPECT
- 6 TO GROUP HEALTH PLANS.—Nothing in this title
- shall be construed to affect or modify the provisions
- 8 of section 514 of the Employee Retirement Income
- 9 Security Act of 1974 with respect to group health
- plans.
- 11 (b) Rules of Construction.—Except as provided
- 12 in sections 152 and 153, nothing in this title shall be con-
- 13 strued as requiring a group health plan or health insur-
- 14 ance coverage to provide specific benefits under the terms
- 15 of such plan or coverage.
- 16 (c) Definitions.—For purposes of this section:
- 17 (1) STATE LAW.—The term "State law" in-
- cludes all laws, decisions, rules, regulations, or other
- 19 State action having the effect of law, of any State.
- A law of the United States applicable only to the
- 21 District of Columbia shall be treated as a State law
- rather than a law of the United States.
- 23 (2) STATE.—The term "State" includes a
- 24 State, the Northern Mariana Islands, any political

- 1 subdivisions of a State or such Islands, or any agen-
- 2 cy or instrumentality of either.
- 3 SEC. 193. REGULATIONS.
- 4 The Secretaries of Health and Human Services,
- 5 Labor, and the Treasury shall issue such regulations as
- 6 may be necessary or appropriate to carry out this title.
- 7 Such regulations shall be issued consistent with section
- 8 104 of Health Insurance Portability and Accountability
- 9 Act of 1996. Such Secretaries may promulgate any in-
- 10 terim final rules as the Secretaries determine are appro-
- 11 priate to carry out this title.
- 12 TITLE II—APPLICATION OF PA-
- 13 TIENT PROTECTION STAND-
- 14 ARDS TO GROUP HEALTH
- 15 PLANS AND HEALTH INSUR-
- 16 ANCE COVERAGE UNDER
- 17 **PUBLIC HEALTH SERVICE**
- 18 **ACT**
- 19 SEC. 201. APPLICATION TO GROUP HEALTH PLANS AND
- 20 GROUP HEALTH INSURANCE COVERAGE.
- 21 (a) In General.—Subpart 2 of part A of title
- 22 XXVII of the Public Health Service Act is amended by
- 23 adding at the end the following new section:

### 1 "SEC. 2706. PATIENT PROTECTION STANDARDS.

- 2 "(a) In General.—Each group health plan shall
- 3 comply with patient protection requirements under title I
- 4 of the Patients' Bill of Rights Act of 1998, and each
- 5 health insurance issuer shall comply with patient protec-
- 6 tion requirements under such title with respect to group
- 7 health insurance coverage it offers, and such requirements
- 8 shall be deemed to be incorporated into this subsection.
- 9 "(b) Notice.—A group health plan shall comply with
- 10 the notice requirement under section 711(d) of the Em-
- 11 ployee Retirement Income Security Act of 1974 with re-
- 12 spect to the requirements referred to in subsection (a) and
- 13 a health insurance issuer shall comply with such notice
- 14 requirement as if such section applied to such issuer and
- 15 such issuer were a group health plan.".
- 16 (b) Conforming Amendment.—Section
- 17 2721(b)(1)(A) of such Act (42 U.S.C. 300gg–21(b)(1)(A))
- 18 is amended by inserting "(other than section 2706)" after
- 19 "requirements of such subparts".
- 20 SEC. 202. APPLICATION TO INDIVIDUAL HEALTH INSUR-
- 21 ANCE COVERAGE.
- 22 Part B of title XXVII of the Public Health Service
- 23 Act is amended by inserting after section 2751 the follow-
- 24 ing new section:

l	"SEC	2752	PATIENT	PROTECTION	STANDARDS

- 2 "(a) In General.—Each health insurance issuer
- 3 shall comply with patient protection requirements under
- 4 title I of the Patients' Bill of Rights Act of 1998 with
- 5 respect to individual health insurance coverage it offers,
- 6 and such requirements shall be deemed to be incorporated
- 7 into this subsection.
- 8 "(b) Notice.—A health insurance issuer under this
- 9 part shall comply with the notice requirement under sec-
- 10 tion 711(d) of the Employee Retirement Income Security
- 11 Act of 1974 with respect to the requirements of such title
- 12 as if such section applied to such issuer and such issuer
- 13 were a group health plan.".
- 14 TITLE III—AMENDMENTS TO
- 15 THE EMPLOYEE RETIREMENT
- 16 INCOME SECURITY ACT OF
- 17 **1974**
- 18 SEC. 301. APPLICATION OF PATIENT PROTECTION STAND-
- 19 ARDS TO GROUP HEALTH PLANS AND GROUP
- 20 HEALTH INSURANCE COVERAGE UNDER THE
- 21 EMPLOYEE RETIREMENT INCOME SECURITY
- 22 **ACT OF 1974.**
- 23 (a) In General.—Subpart B of part 7 of subtitle
- 24 B of title I of the Employee Retirement Income Security
- 25 Act of 1974 is amended by adding at the end the following
- 26 new section:

# 1 "SEC. 713. PATIENT PROTECTION STANDARDS.

2	"(a) In General.—Subject to subsection (b), a
3	group health plan (and a health insurance issuer offering
4	group health insurance coverage in connection with such
5	a plan) shall comply with the requirements of title I of
6	the Patients' Bill of Rights Act of 1998 (as in effect as
7	of the date of the enactment of such Act), and such re-
8	quirements shall be deemed to be incorporated into this
9	subsection.
10	"(b) Plan Satisfaction of Certain Require-
11	MENTS.—
12	"(1) Satisfaction of certain require-
13	MENTS THROUGH INSURANCE.—For purposes of
14	subsection (a), insofar as a group health plan pro-
15	vides benefits in the form of health insurance cov-
16	erage through a health insurance issuer, the plan
17	shall be treated as meeting the following require-
18	ments of title I of the Patients' Bill of Rights Act
19	of 1998 with respect to such benefits and not be
20	considered as failing to meet such requirements be-
21	cause of a failure of the issuer to meet such require-
22	ments so long as the plan sponsor or its representa-
23	tives did not cause such failure by the issuer:
24	"(A) Section 101 (relating to access to
25	emergency care).

1	"(B) Section 102(a)(1) (relating to offer-
2	ing option to purchase point-of-service cov-
3	erage), but only insofar as the plan is meeting
4	such requirement through an agreement with
5	the issuer to offer the option to purchase point-
6	of-service coverage under such section.
7	"(C) Section 103 (relating to choice of pro-
8	viders).
9	"(D) Section 104 (relating to access to
10	specialty care).
11	"(E) Section 105(a)(1) (relating to con-
12	tinuity in case of termination of provider con-
13	tract) and section 105(a)(2) (relating to con-
14	tinuity in case of termination of issuer con-
15	tract), but only insofar as a replacement issuer
16	assumes the obligation for continuity of care.
17	"(F) Section 106 (relating to coverage for
18	individuals participating in approved clinical
19	trials.)
20	"(G) Section 107 (relating to access to
21	needed prescription drugs).
22	"(H) Section 108 (relating to adequacy of
23	provider network).
24	"(I) Subtitle B (relating to quality assur-
25	ance).

1	"(J) Section 143 (relating to additional
2	rules regarding participation of health care pro-
3	fessionals).
4	"(K) Section 152 (relating to standards re-

- "(K) Section 152 (relating to standards relating to benefits for certain breast cancer treatment).
- "(L) Section 153 (relating to standards relating to benefits for reconstructive breast surgery).
- "(2) Information.—With respect to information required to be provided or made available under section 121, in the case of a group health plan that provides benefits in the form of health insurance coverage through a health insurance issuer, the Secretary shall determine the circumstances under which the plan is not required to provide or make available the information (and is not liable for the issuer's failure to provide or make available the information), if the issuer is obligated to provide and make available (or provides and makes available) such information.
- "(3) GRIEVANCE AND INTERNAL APPEALS.— With respect to the grievance system and internal appeals process required to be established under sections 131 and 132, in the case of a group health

- plan that provides benefits in the form of health insurance coverage through a health insurance issuer, the Secretary shall determine the circumstances under which the plan is not required to provide for such system and process (and is not liable for the issuer's failure to provide for such system and process), if the issuer is obligated to provide for (and provides for) such system and process.
  - "(4) External appeals.—Pursuant to rules of the Secretary, insofar as a group health plan enters into a contract with a qualified external appeal entity for the conduct of external appeal activities in accordance with section 133, the plan shall be treated as meeting the requirement of such section and is not liable for the entity's failure to meet any requirements under such section.
  - "(5) APPLICATION TO PROHIBITIONS.—Pursuant to rules of the Secretary, if a health insurance issuer offers health insurance coverage in connection with a group health plan and takes an action in violation of any of the following sections, the group health plan shall not be liable for such violation unless the plan caused such violation:
- 24 "(A) Section 109 (relating to non-25 discrimination in delivery of services).

1	"(B) Section 141 (relating to prohibition
2	of interference with certain medical communica-
3	tions).
4	"(C) Section 142 (relating to prohibition
5	against transfer of indemnification or improper
6	incentive arrangements).
7	"(D) Section 144 (relating to prohibition
8	on retaliation).
9	"(E) Section 151 (relating to promoting
10	good medical practice).
11	"(6) Construction.—Nothing in this sub-
12	section shall be construed to affect or modify the re-
13	sponsibilities of the fiduciaries of a group health
14	plan under part 4 of subtitle B.
15	"(7) Application to certain prohibitions
16	AGAINST RETALIATION.—With respect to compliance
17	with the requirements of section $144(b)(1)$ of the
18	Patients' Bill of Rights Act of 1998, for purposes of
19	this subtitle the term 'group health plan' is deemed
20	to include a reference to an institutional health care
21	provider.
22	"(c) Enforcement of Certain Requirements.—
23	"(1) Complaints.—Any protected health care
24	professional who believes that the professional has
25	been retaliated or discriminated against in violation

- of section 144(b)(1) of the Patients' Bill of Rights
- 2 Act of 1998 may file with the Secretary a complaint
- within 180 days of the date of the alleged retaliation
- 4 or discrimination.
- 5 "(2) Investigation.—The Secretary shall in-
- 6 vestigate such complaints and shall determine if a
- 7 violation of such section has occurred and, if so,
- 8 shall issue an order to ensure that the protected
- 9 health care professional does not suffer any loss of
- position, pay, or benefits in relation to the plan,
- issuer, or provider involved, as a result of the viola-
- tion found by the Secretary.
- 13 "(d) Conforming Regulations.—The Secretary
- 14 may issue regulations to coordinate the requirements on
- 15 group health plans under this section with the require-
- 16 ments imposed under the other provisions of this title.".
- 17 (b) Satisfaction of ERISA Claims Procedure
- 18 REQUIREMENT.—Section 503 of such Act (29 U.S.C.
- 19 1133) is amended by inserting "(a)" after "Sec. 503."
- 20 and by adding at the end the following new subsection:
- 21 "(b) In the case of a group health plan (as defined
- 22 in section 733) compliance with the requirements of sub-
- 23 title D (and section 115) of title I of the Patients' Bill
- 24 of Rights Act of 1998 in the case of a claims denial shall

- 1 be deemed compliance with subsection (a) with respect to
- 2 such claims denial.".
- 3 (c) Conforming Amendments.—(1) Section 732(a)
- 4 of such Act (29 U.S.C. 1185(a)) is amended by striking
- 5 "section 711" and inserting "sections 711 and 713".
- 6 (2) The table of contents in section 1 of such Act
- 7 is amended by inserting after the item relating to section
- 8 712 the following new item:
  - "Sec. 713. Patient protection standards.".
- 9 (3) Section 502(b)(3) of such Act (29 U.S.C.
- 10 1132(b)(3)) is amended by inserting "(other than section
- 11 144(b))" after "part 7".
- 12 SEC. 302. ERISA PREEMPTION NOT TO APPLY TO CERTAIN
- 13 ACTIONS INVOLVING HEALTH INSURANCE
- 14 POLICYHOLDERS.
- 15 (a) In General.—Section 514 of the Employee Re-
- 16 tirement Income Security Act of 1974 (29 U.S.C. 1144)
- 17 is amended by adding at the end the following subsection:
- 18 "(e) Preemption Not To Apply to Certain Ac-
- 19 TIONS ARISING OUT OF PROVISION OF HEALTH BENE-
- 20 FITS.—
- 21 "(1) IN GENERAL.—Except as provided in this
- subsection, nothing in this title shall be construed to
- 23 invalidate, impair, or supersede any cause of action
- 24 under State law to recover damages resulting from

1	personal injury or for wrongful death against any
2	person—
3	"(A) in connection with the provision of in-
4	surance, administrative services, or medical
5	services by such person to or for a group health
6	plan (as defined in section 733), or
7	"(B) that arises out of the arrangement by
8	such person for the provision of such insurance,
9	administrative services, or medical services by
10	other persons.
11	"(2) Exception for employers and other
12	PLAN SPONSORS.—
13	"(A) In general.—Subject to subpara-
14	graph (B), paragraph (1) does not authorize—
15	"(i) any cause of action against an
16	employer or other plan sponsor maintain-
17	ing the group health plan, or
18	"(ii) a right of recovery or indemnity
19	by a person against an employer or other
20	plan sponsor for damages assessed against
21	the person pursuant to a cause of action
22	under paragraph (1).
23	"(B) Special Rule.—Subparagraph (A)
24	shall not preclude any cause of action described

1	in paragraph (1) against an employer or other
2	plan sponsor if—
3	"(i) such action is based on the em-
4	ployer's or other plan sponsor's exercise of
5	discretionary authority to make a decision
6	on a claim for benefits covered under the
7	plan or health insurance coverage in the
8	case at issue; and
9	"(ii) the exercise by such employer or
10	other plan sponsor of such authority re-
11	sulted in personal injury or wrongful
12	death.".
13	(b) Effective Date.—The amendment made by
14	subsection (a) shall apply to acts and omissions occurring
15	on or after the date of the enactment of this Act from
16	which a cause of action arises.
17	TITLE IV—APPLICATION TO
18	GROUP HEALTH PLANS
19	UNDER THE INTERNAL REVE-
20	NUE CODE OF 1986.
21	SEC. 401. AMENDMENTS TO THE INTERNAL REVENUE CODE
22	OF 1986.
23	Subchapter B of chapter 100 of the Internal Revenue
24	Code of 1986 (as amended by section 1531(a) of the Tax-
25	payer Relief Act of 1997) is amended—

1	(1) in the table of sections, by inserting after
2	the item relating to section 9812 the following new
3	item:
	"Sec. 9813. Standard relating to patient freedom of choice."; and
4	(2) by inserting after section 9812 the follow-
5	ing:
6	"SEC. 9813. STANDARD RELATING TO PATIENTS' BILL OF
7	RIGHTS.
8	"A group health plan shall comply with the require-
9	ments of title I of the Patients' Bill of Rights Act of 1998
10	(as in effect as of the date of the enactment of such Act),
11	and such requirements shall be deemed to be incorporated
12	into this section.".
13	TITLE V—EFFECTIVE DATES; CO-
14	ORDINATION IN IMPLEMEN-
15	TATION
16	SEC. 501. EFFECTIVE DATES.
17	(a) Group Health Coverage.—
18	(1) In general.—Subject to paragraph (2),
19	the amendments made by sections 201(a), 301, and
20	401 (and title I insofar as it relates to such sections)
21	shall apply with respect to group health plans, and
22	health insurance coverage offered in connection with
23	group health plans, for plan years beginning on or
24	after January 1, 1999 (in this section referred to as

- the "general effective date") and also shall apply to portions of plan years occurring on and after such date.
  - (2) Treatment of collective bargaining agreements between employee representatives and 1 or more employers ratified before the date of enactment of this Act, the amendments made by sections 201(a), 301, and 401 (and title I insofar as it relates to such sections) shall not apply to plan years beginning before the later of—
    - (A) the date on which the last collective bargaining agreements relating to the plan terminates (determined without regard to any extension thereof agreed to after the date of enactment of this Act), or
    - (B) the general effective date.

For purposes of subparagraph (A), any plan amendment made pursuant to a collective bargaining agreement relating to the plan which amends the plan solely to conform to any requirement added by this Act shall not be treated as a termination of such collective bargaining agreement.

- 1 (b) Individual Health Insurance Coverage.—
- 2 The amendments made by section 202 shall apply with
- 3 respect to individual health insurance coverage offered,
- 4 sold, issued, renewed, in effect, or operated in the individ-
- 5 ual market on or after the general effective date.

### 6 SEC. 502. COORDINATION IN IMPLEMENTATION.

- 7 Section 104(1) of Health Insurance Portability and
- 8 Accountability Act of 1996 is amended by striking "this
- 9 subtitle (and the amendments made by this subtitle and
- 10 section 401)" and inserting "the provisions of part 7 of
- 11 subtitle B of title I of the Employee Retirement Income
- 12 Security Act of 1974, the provisions of parts A and C of
- 13 title XXVII of the Public Health Service Act, chapter 100
- 14 of the Internal Revenue Code of 1986, and title I of the
- 15 Patients' Bill of Rights Act of 1998".

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